US007776005B2

(12) **United States Patent**
Haggstrom et al.

(10) **Patent No.: US 7,776,005 B2**
(45) **Date of Patent: *Aug. 17, 2010**

(54) **TRIPLE LUMEN CATHETER WITH OCCLUSION RESISTANT TIP**

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(73) Assignee: **Covidien AG** (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1661 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/873,094**

(22) Filed: **Jun. 21, 2004**

(65) **Prior Publication Data**

US 2005/0033222 A1 Feb. 10, 2005

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/602,897, filed on Jun. 24, 2003, now Pat. No. 7,141,035, which is a continuation-in-part of application No. PCT/US03/09687, filed on Mar. 28, 2003.

(51) **Int. Cl.**
A61M 3/00 (2006.01)

(52) **U.S. Cl.** **604/43**

(58) **Field of Classification Search** 604/39–43, 604/523, 528, 264, 93.01, 910
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

701,075	A	5/1902	McCully	
2,541,691	A	2/1951	Eicher	
D208,838	S	10/1967	St. Amand	D83/1
4,134,402	A	1/1979	Mahurkar	128/214 R
D254,270	S	2/1980	Ziegler	D24/23
D272,651	S	2/1984	Mahurkar	D24/54
4,443,333	A	4/1984	Mahurkar	210/87
4,568,329	A	2/1986	Mahurkar	604/43
4,583,968	A	4/1986	Mahurkar	604/43
4,601,697	A	7/1986	Mammolenti et al.	604/43
4,604,379	A	8/1986	Twardowski et al.	514/21
D289,682	S	5/1987	Dragan	D24/16
4,675,004	A	6/1987	Hadford et al.	604/44
4,682,978	A	7/1987	Martin	604/43

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2 326 941	10/1976

(Continued)

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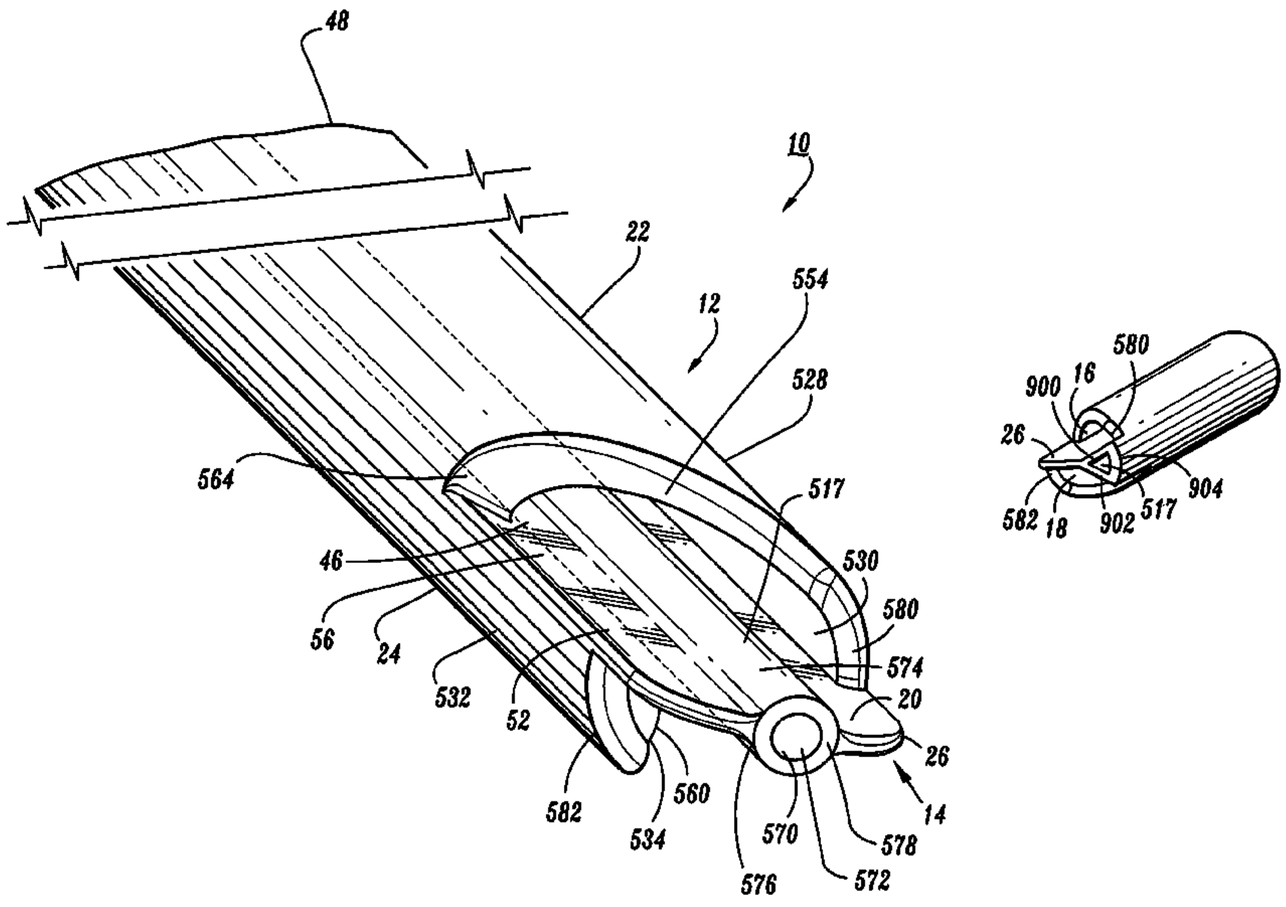
Assistant Examiner—Christopher D Koharski
(74) *Attorney, Agent, or Firm*—Thomas M. Johnston, Esq.

(57) **ABSTRACT**

A catheter is provided that includes an elongated tubular body extending to a distal end. The tubular body has a first and a second lumen with a septum disposed therebetween. The tubular body includes a first wall that defines the first lumen and a second wall that defines the second lumen. A portion of the septum extends distally beyond the first lumen and the second lumen. The first wall includes a first wall extension that extends distally beyond the first lumen and is spaced apart from the portion of the septum. The first wall extension defines a concave surface facing the portion of the septum. In an alternate embodiment, the catheter includes a tip with spiraled configuration. The catheter may include a third lumen.

31 Claims, 18 Drawing Sheets



U.S. PATENT DOCUMENTS

4,687,471	A		8/1987	Twardowski et al.	604/175
4,692,141	A		9/1987	Mahurkar	604/43
D292,825	S		11/1987	Dragan	D24/16
4,770,652	A		9/1988	Mahurkar	604/4
4,772,269	A		9/1988	Twardowski et al.	604/175
D298,461	S		11/1988	Manno	D24/51
4,808,155	A		2/1989	Mahurkar	604/43
4,842,582	A		6/1989	Mahurkar	604/43
4,883,426	A		11/1989	Ferrer	433/91
4,894,057	A	*	1/1990	Howes	604/523
4,895,561	A		1/1990	Mahurkar	604/43
4,904,238	A		2/1990	Williams	604/43
D312,872	S		12/1990	Mähl	D24/10
5,009,636	A		4/1991	Wortley et al.	604/43
5,015,184	A		5/1991	Perry et al.	433/93
5,167,623	A	*	12/1992	Cianci et al.	604/43
5,171,227	A		12/1992	Twardowski et al.	604/175
5,197,951	A		3/1993	Mahurkar	604/93
5,209,723	A		5/1993	Twardowski et al.	604/43
5,221,255	A		6/1993	Mahurkar	604/43
5,221,256	A		6/1993	Mahurkar	604/43
5,273,527	A		12/1993	Schatz et al.	604/43
5,281,134	A		1/1994	Schultz	433/29
5,282,788	A		2/1994	Wilk et al.	604/49
5,290,282	A		3/1994	Casscells	606/29
5,318,518	A		6/1994	Plechinger et al.	604/43
5,336,165	A		8/1994	Twardowski	604/5
5,374,245	A		12/1994	Mahurkar	604/43
5,378,230	A		1/1995	Mahurkar	604/43
5,403,291	A		4/1995	Abrahamson	604/280
5,405,320	A		4/1995	Twardowski	604/43
5,405,341	A		4/1995	Martin	604/284
5,419,777	A		5/1995	Hofling	604/264
5,451,216	A		9/1995	Quinn	604/270
5,464,398	A		11/1995	Haindl	604/280
5,484,397	A		1/1996	Twardowski	604/5
5,486,159	A		1/1996	Mahurkar	604/4
5,509,897	A		4/1996	Twardowski et al.	604/43
5,536,234	A		7/1996	Newman	600/104
5,549,541	A		8/1996	Muller	600/105
5,554,136	A		9/1996	Luther	604/264
5,562,640	A		10/1996	McCabe et al.	604/280
5,569,182	A		10/1996	Twardowski et al.	604/43
5,571,093	A		11/1996	Cruz et al.	604/270
5,607,440	A		3/1997	Danks et al.	606/185
5,685,867	A		11/1997	Twardowski et al.	604/280
5,707,351	A		1/1998	Dorsey, III	604/30
5,725,495	A		3/1998	Strukel et al.	604/44
5,776,092	A		7/1998	Farin et al.	604/22
5,782,797	A		7/1998	Schweich, Jr. et al.	604/49
5,785,678	A		7/1998	Griep et al.	604/28
5,788,680	A		8/1998	Linder	604/280
5,788,681	A		8/1998	Weaver et al.	604/280
5,801,012	A		9/1998	Soff et al.	435/68.1
5,830,196	A		11/1998	Hicks	604/280
5,858,009	A		1/1999	Jonkman	604/264
5,902,476	A		5/1999	Twardowski	210/143
5,961,486	A		10/1999	Twardowski et al.	604/43
6,063,099	A		5/2000	Danks et al.	606/185
6,086,565	A		7/2000	Ouchi	604/187
6,126,631	A		10/2000	Loggie	604/43
6,132,616	A		10/2000	Twardowski et al.	210/646
6,146,536	A		11/2000	Twardowski	210/646
6,152,910	A		11/2000	Agro et al.	604/523
6,190,357	B1		2/2001	Ferrari et al.	604/102.01
6,299,444	B1		10/2001	Cohen	433/91
6,409,700	B1		6/2002	Siegel, Jr. et al.	604/43
6,423,050	B1		7/2002	Twardowski	604/500
6,428,502	B1		8/2002	Lang	604/28
6,576,609	B1		6/2003	Soff et al.	514/12
6,592,565	B2		7/2003	Twardowski	604/500
7,141,035	B2	*	11/2006	Haggstrom	604/43
2002/0065492	A1		5/2002	McGuckin, Jr. et al.	

FOREIGN PATENT DOCUMENTS

CA	2 389 227	A1	10/2001
EP	0107810		5/1984
EP	0341721		11/1989
EP	0555780		8/1993
EP	0623356		11/1994
FR	2 326 941		10/1976
GB	2028136		3/1980
JP	08103492		4/1996
JP	8-308933		11/1996
WO	WO 92/14500		9/1992
WO	WO 95/10317		4/1995
WO	WO 99/38550		8/1999

* cited by examiner

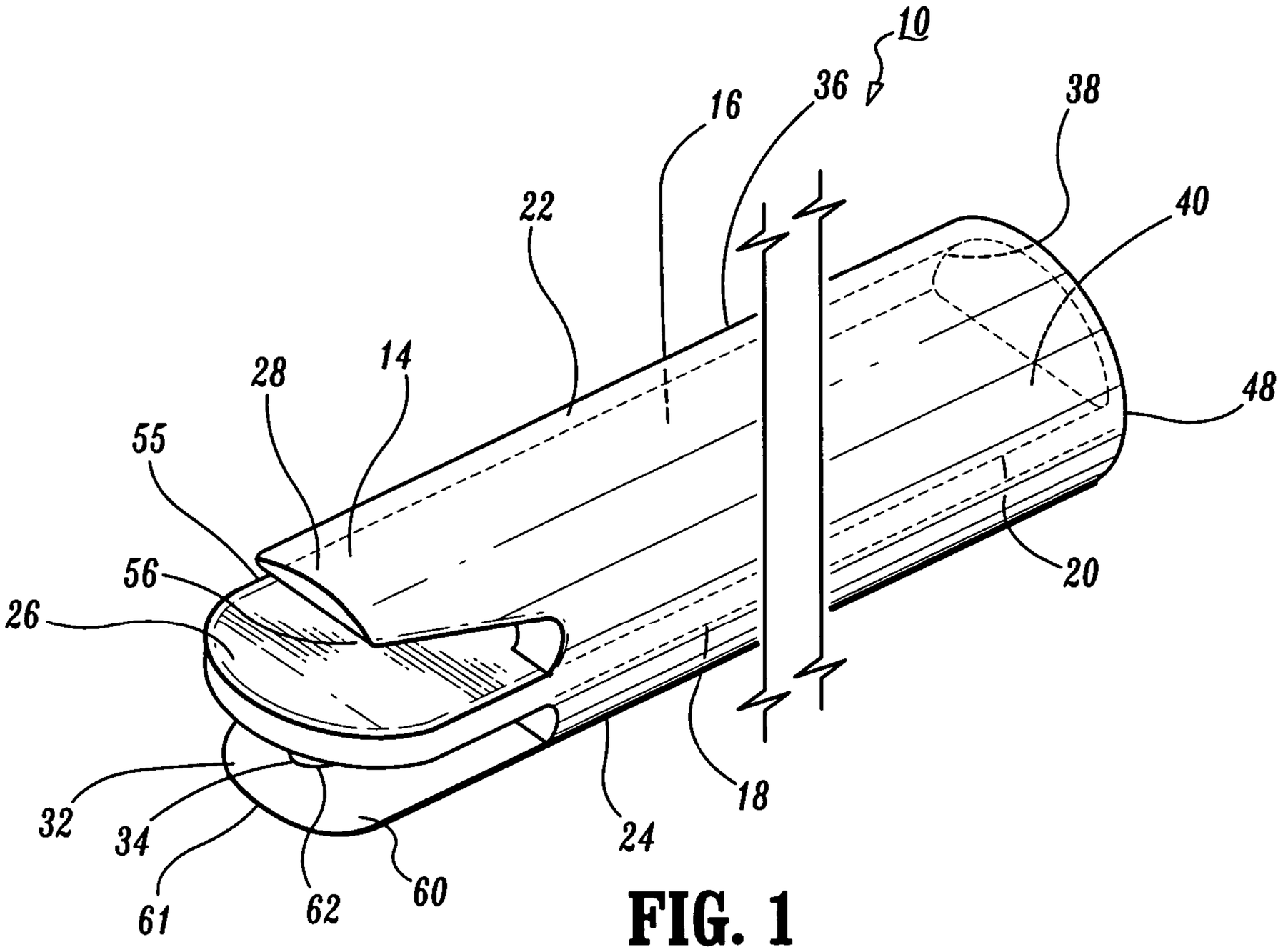

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FIG. 1

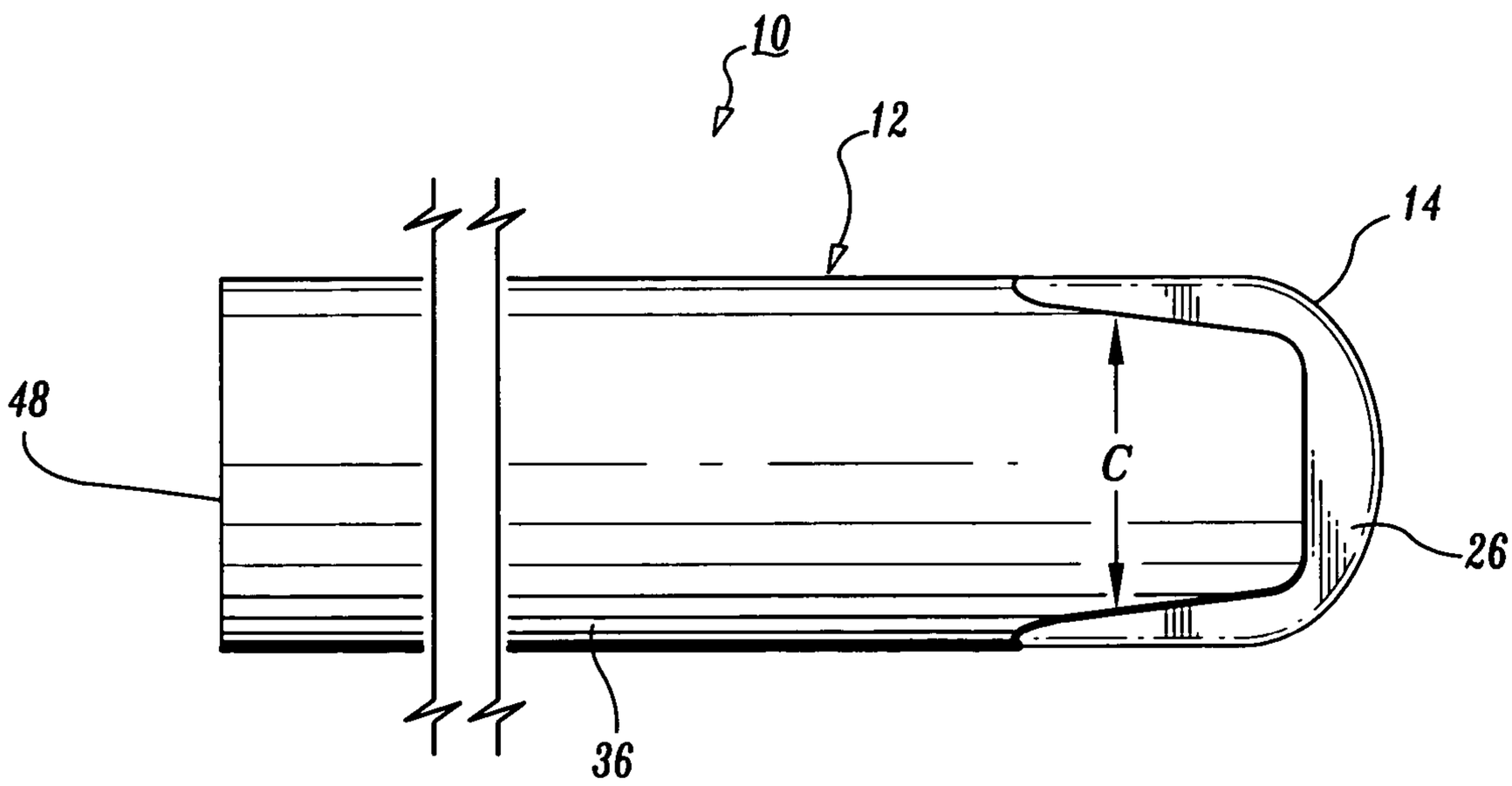
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FIG. 2

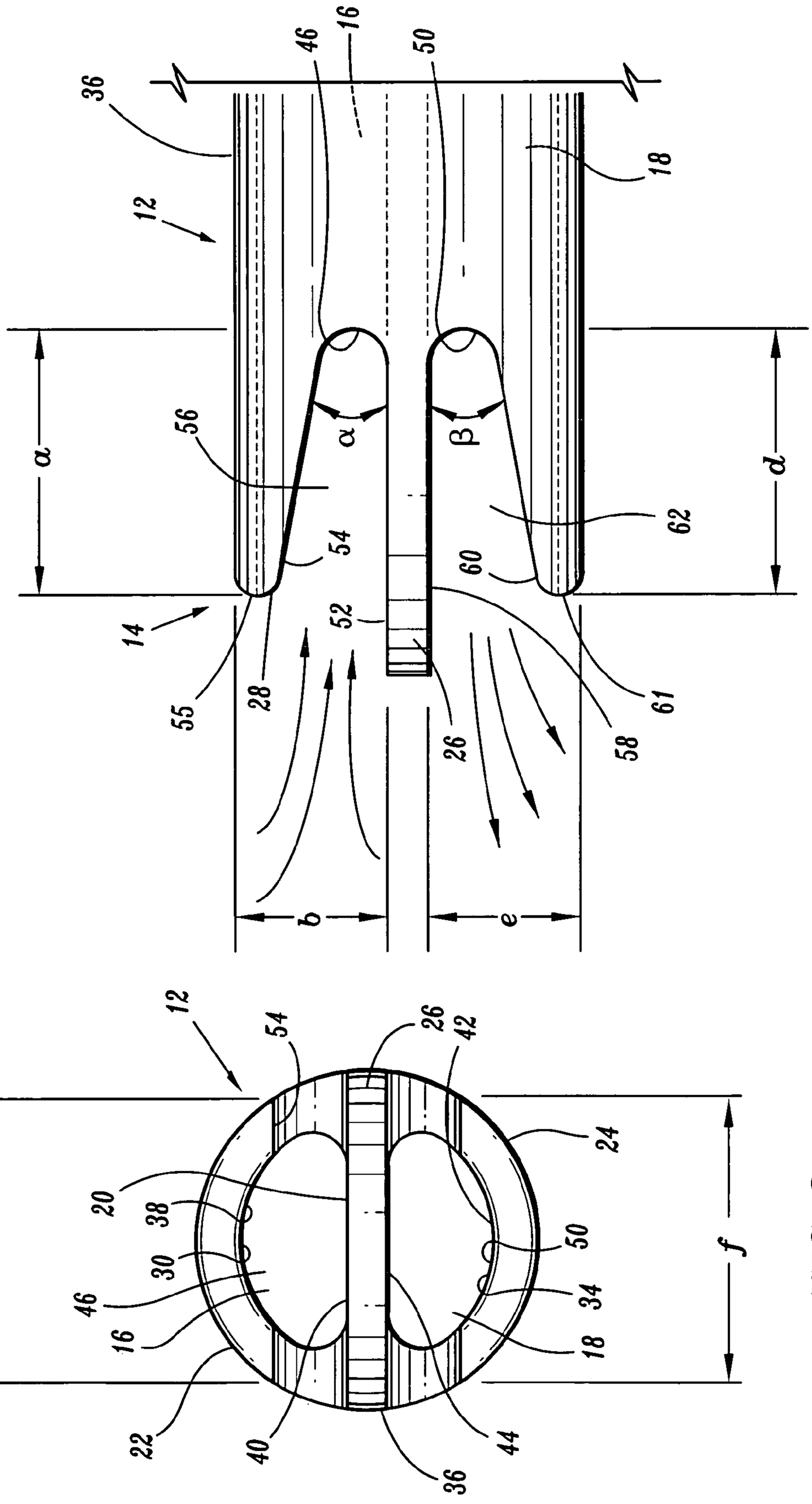
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FIG. 4

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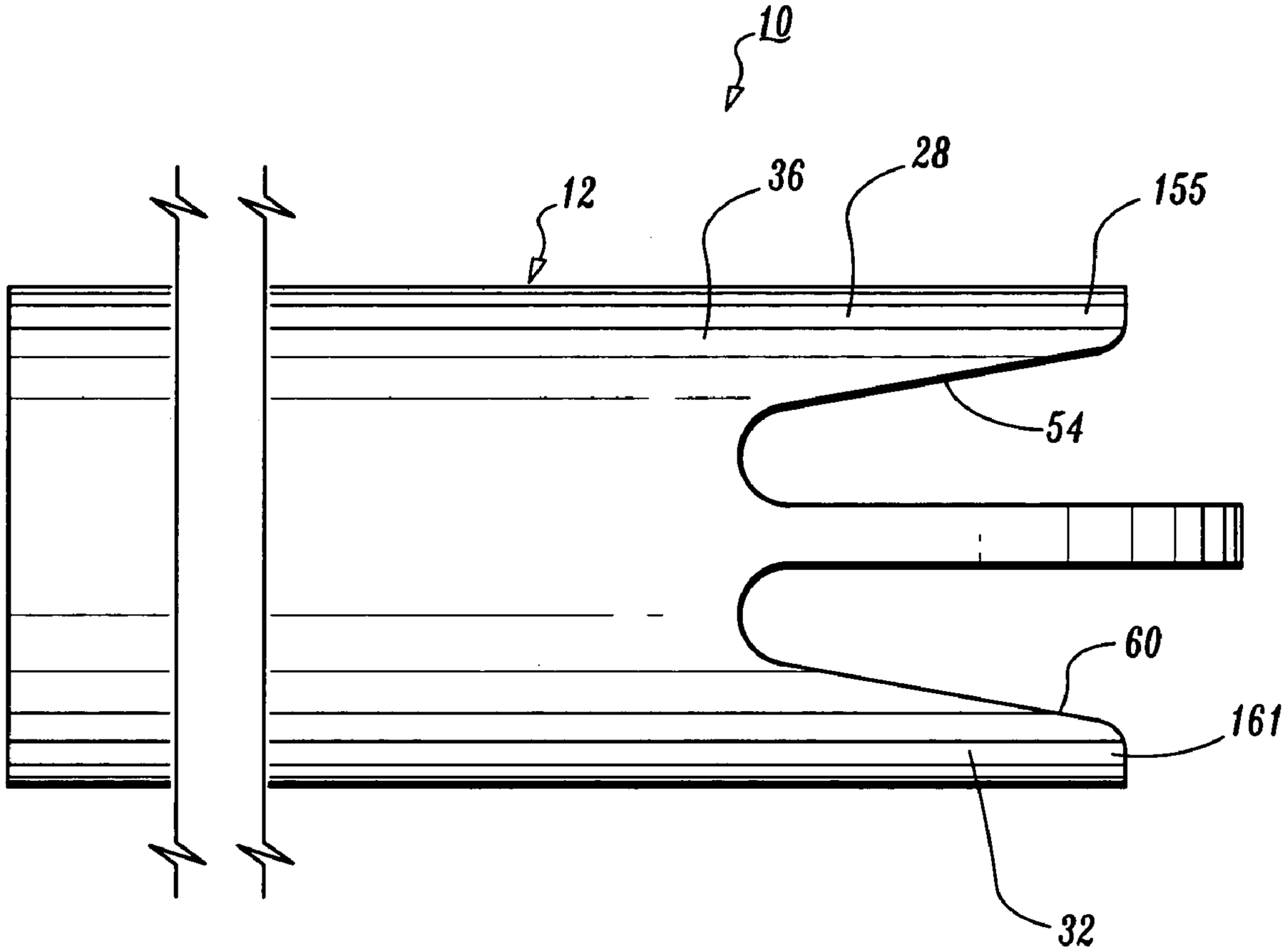
FIG. 3



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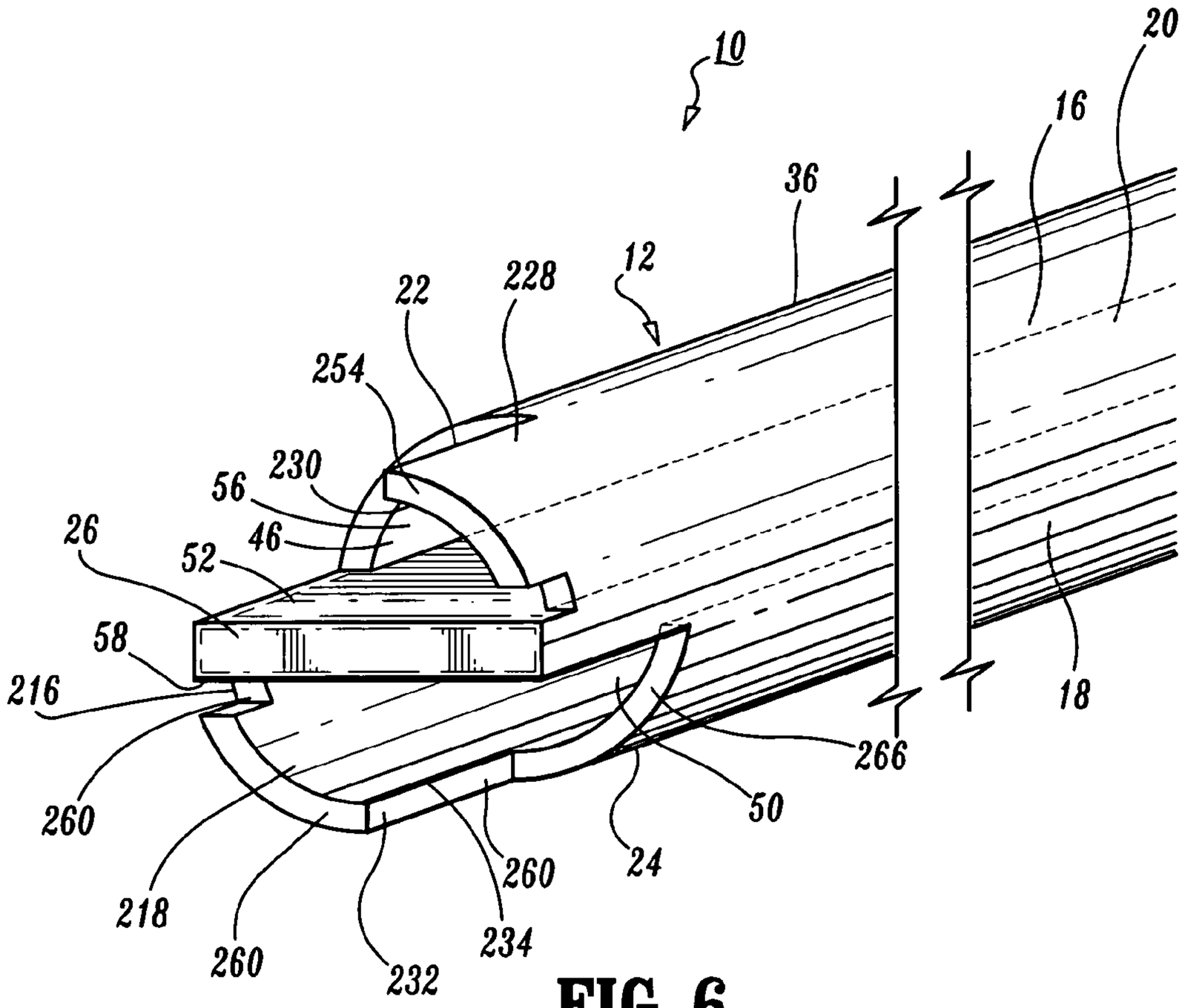
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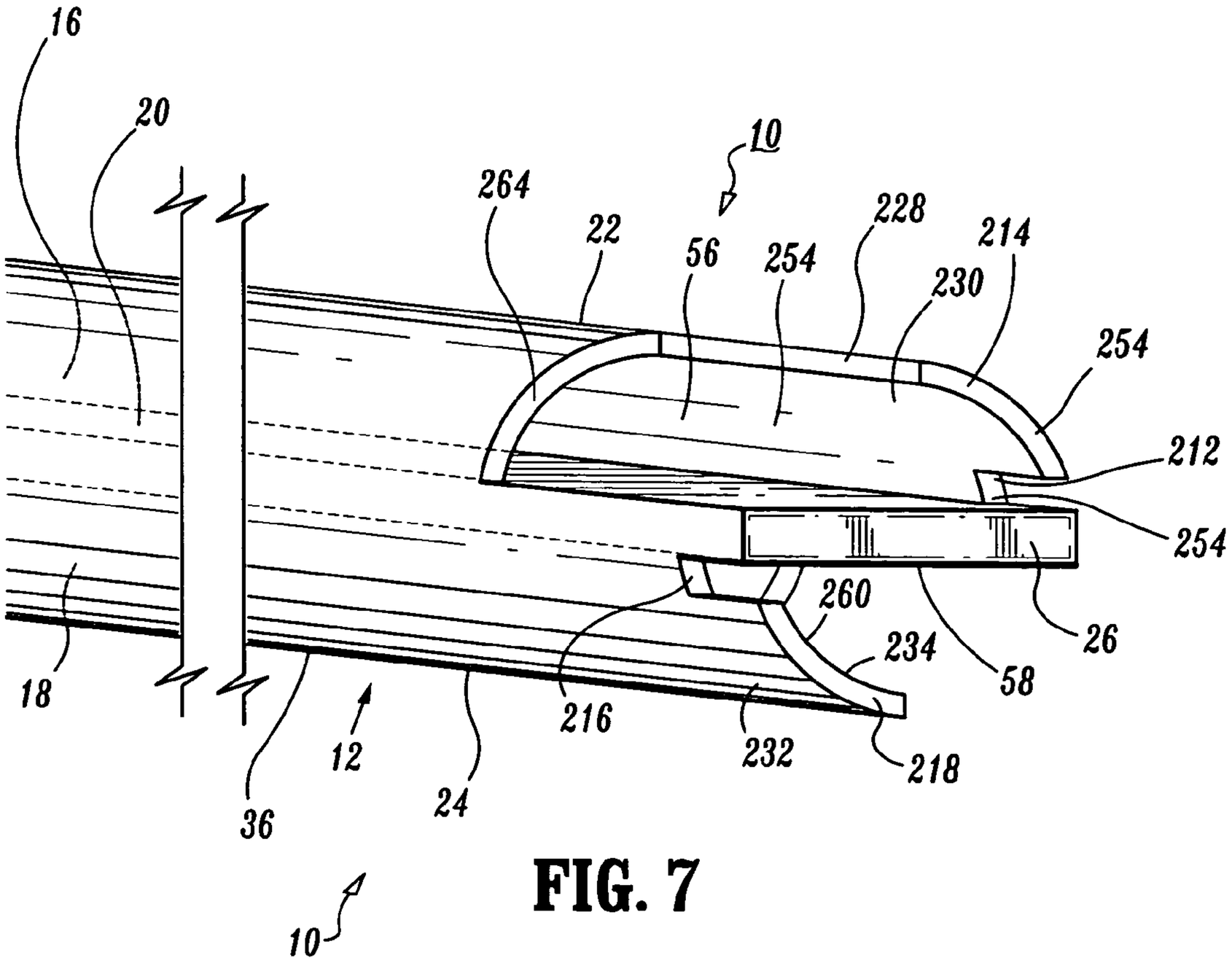
FIG. 6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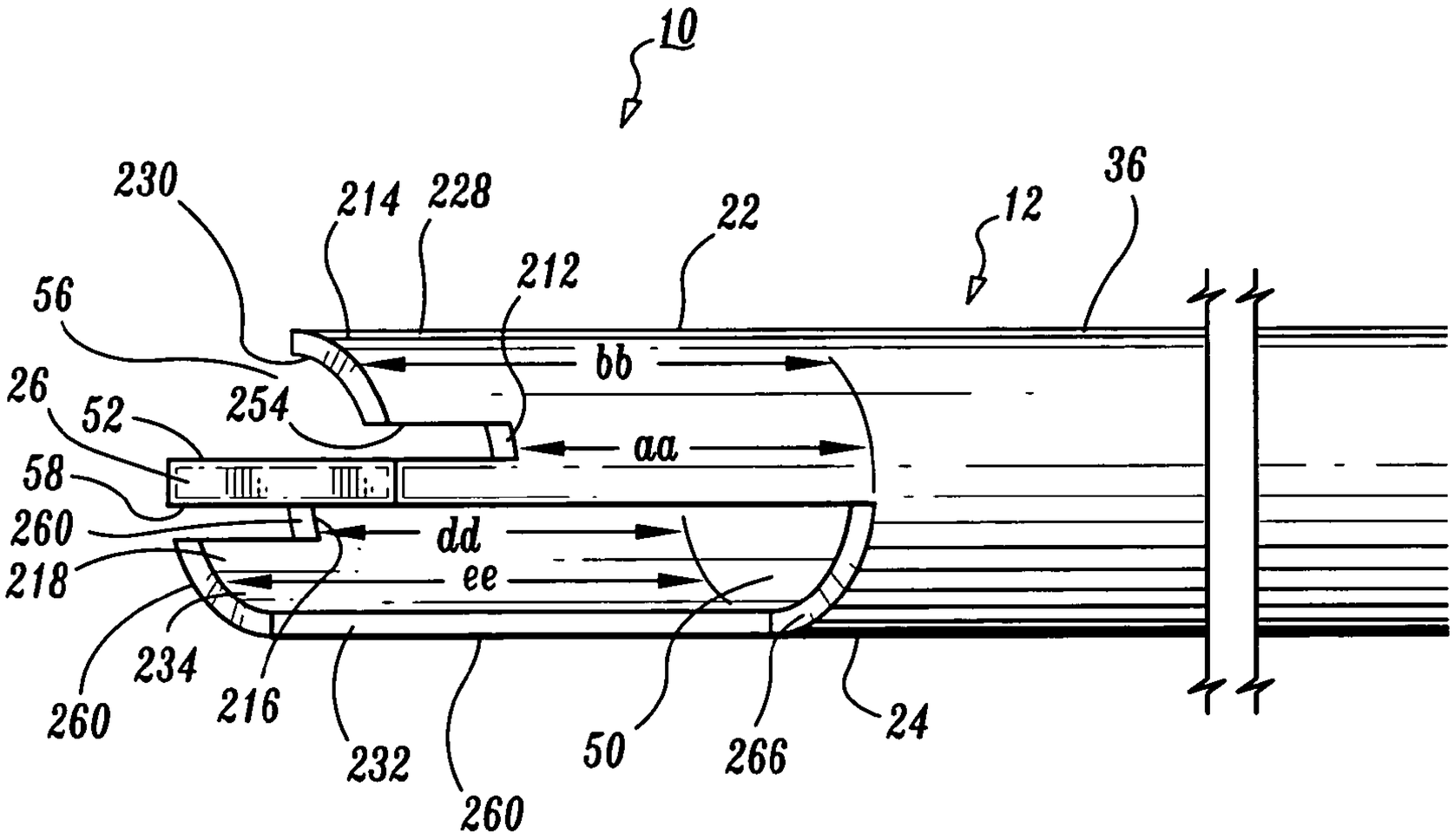
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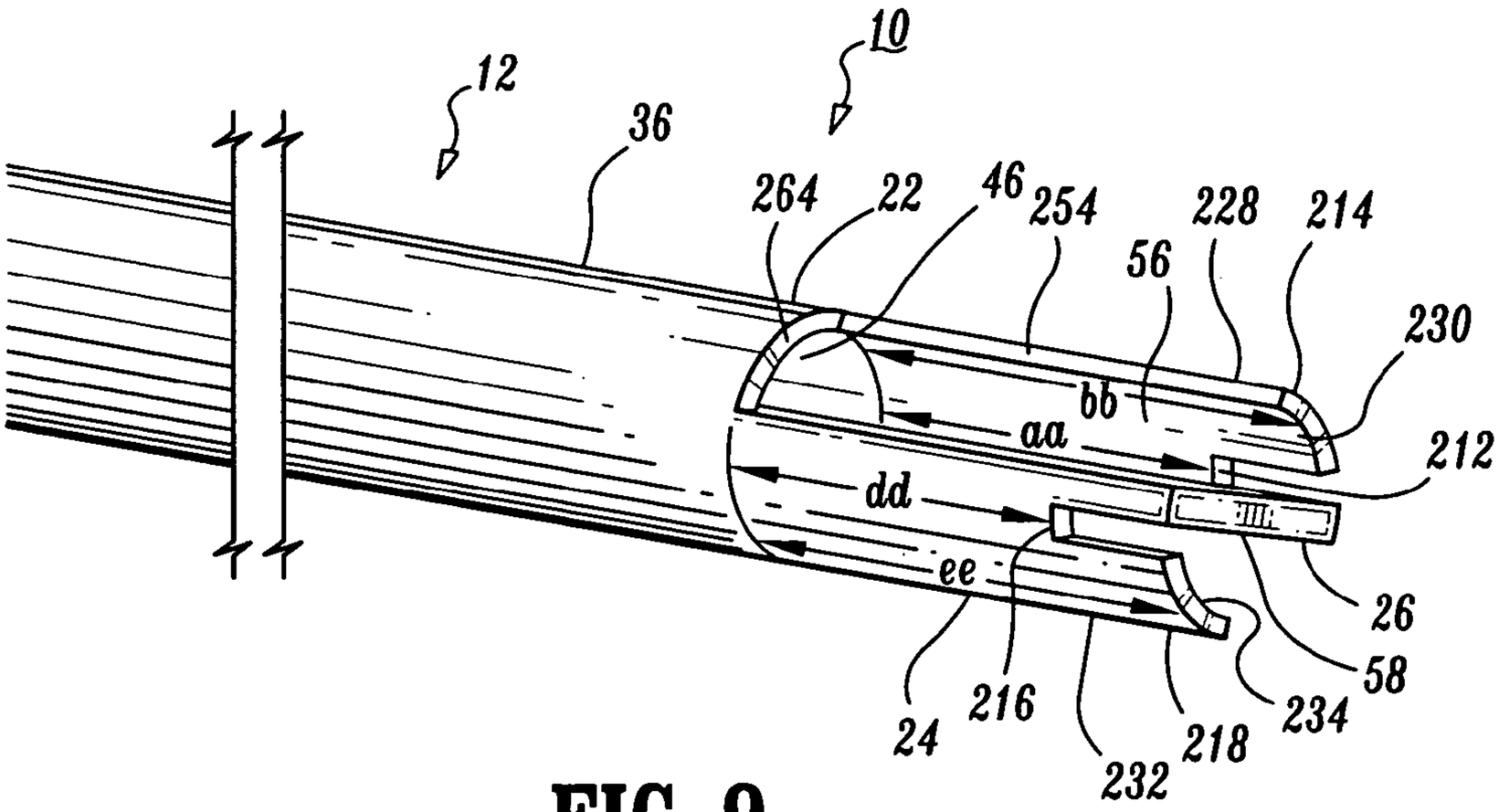
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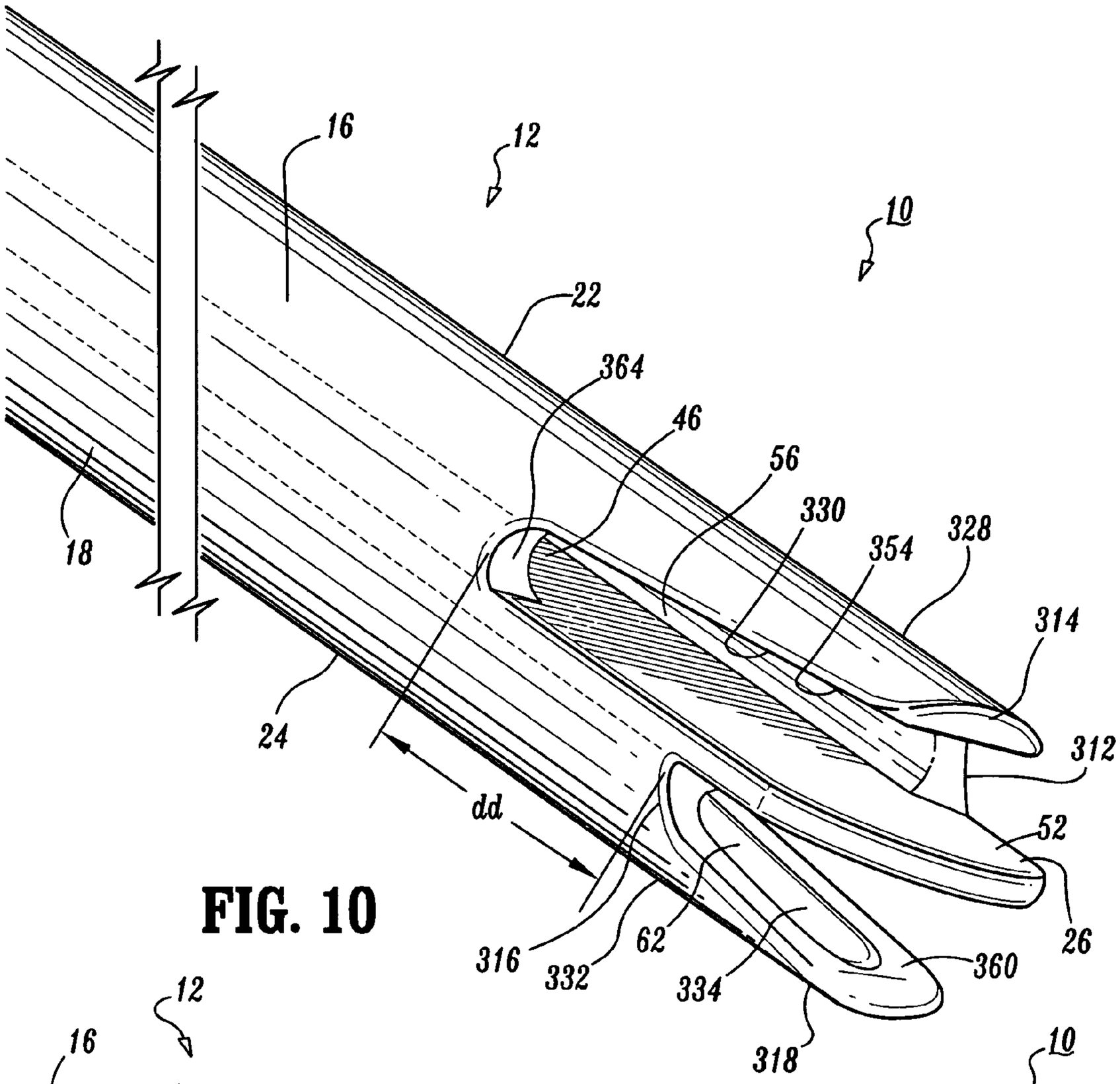
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FIG. 10

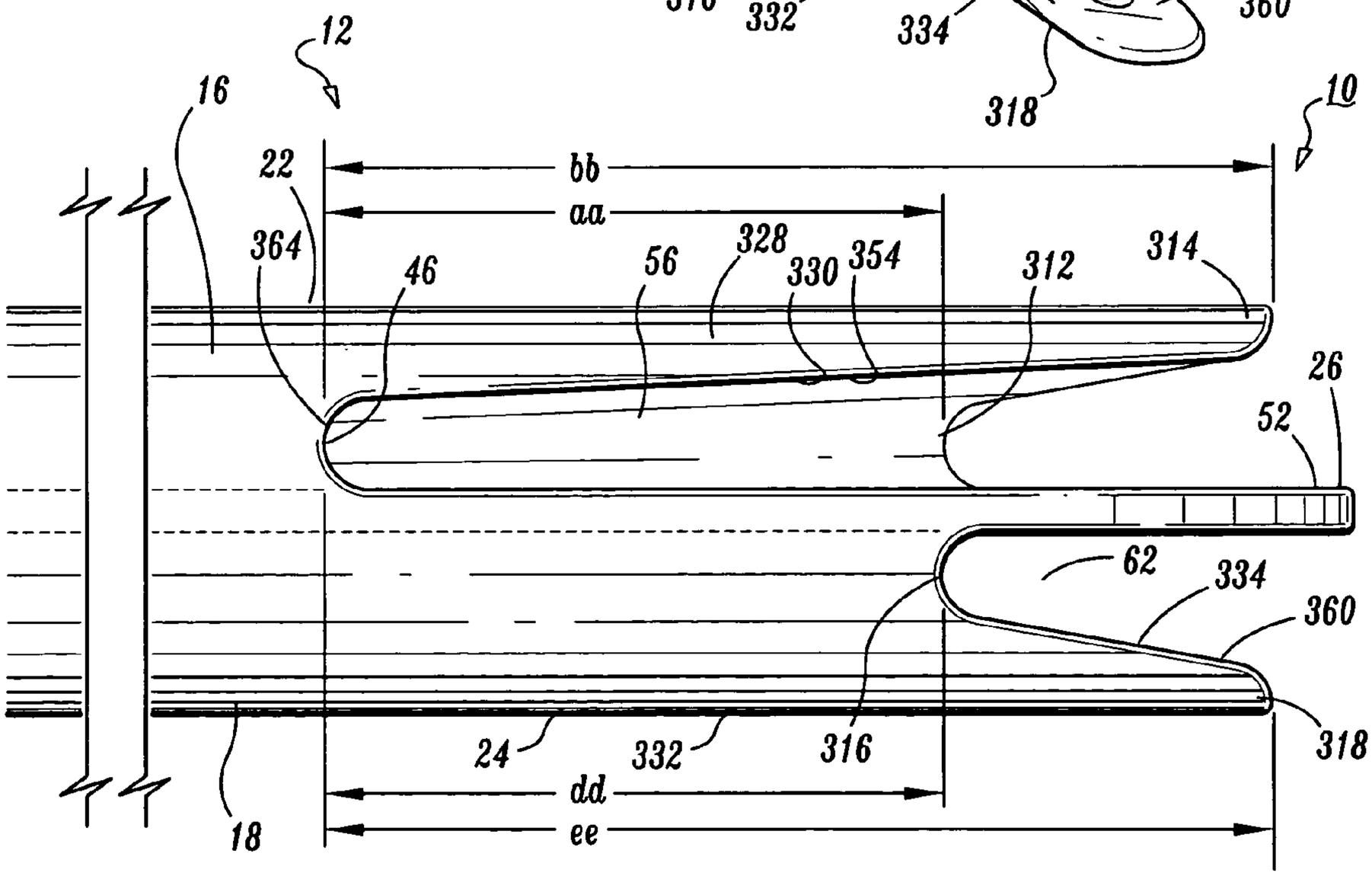
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FIG. 11

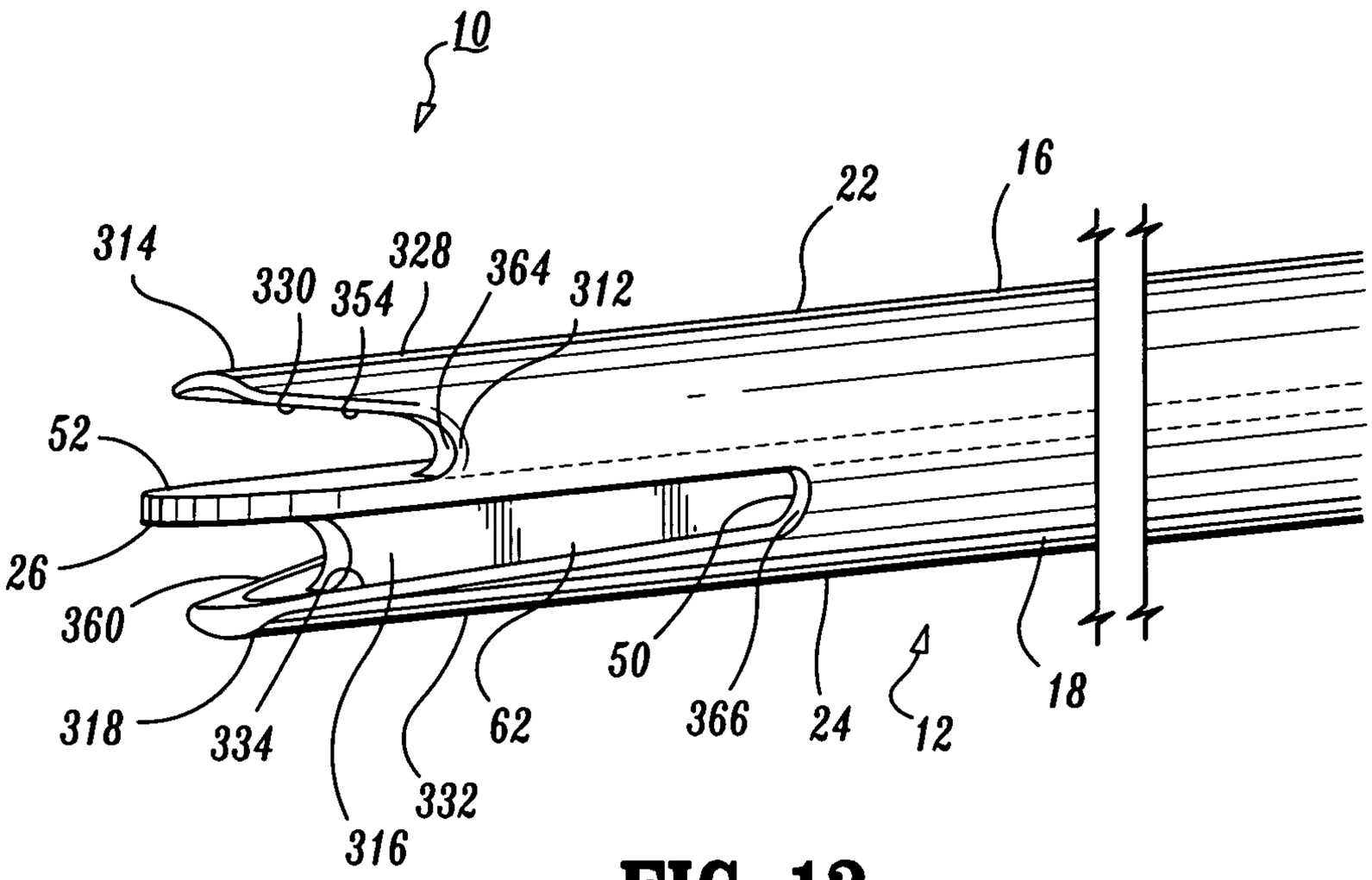
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FIG. 12

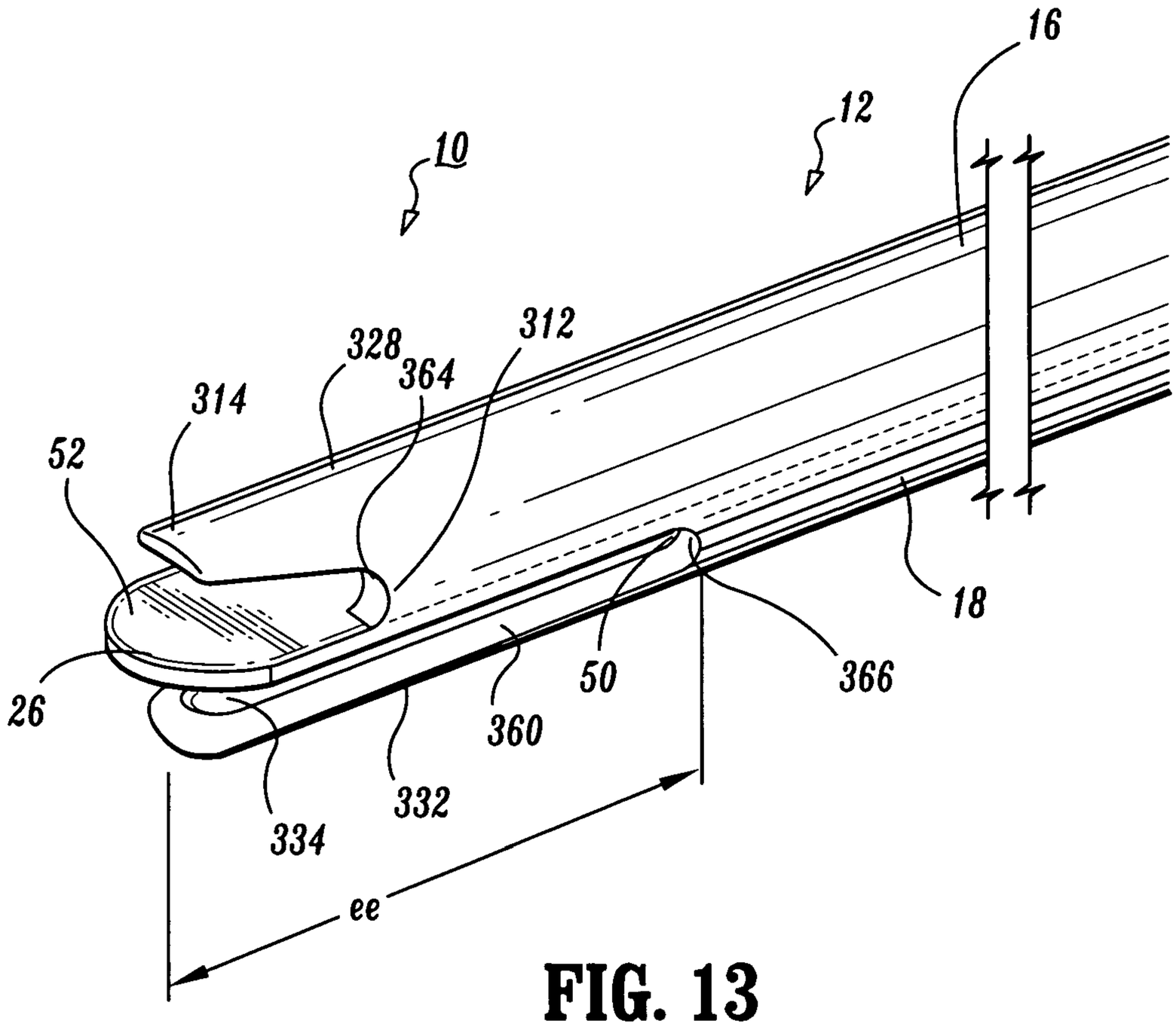
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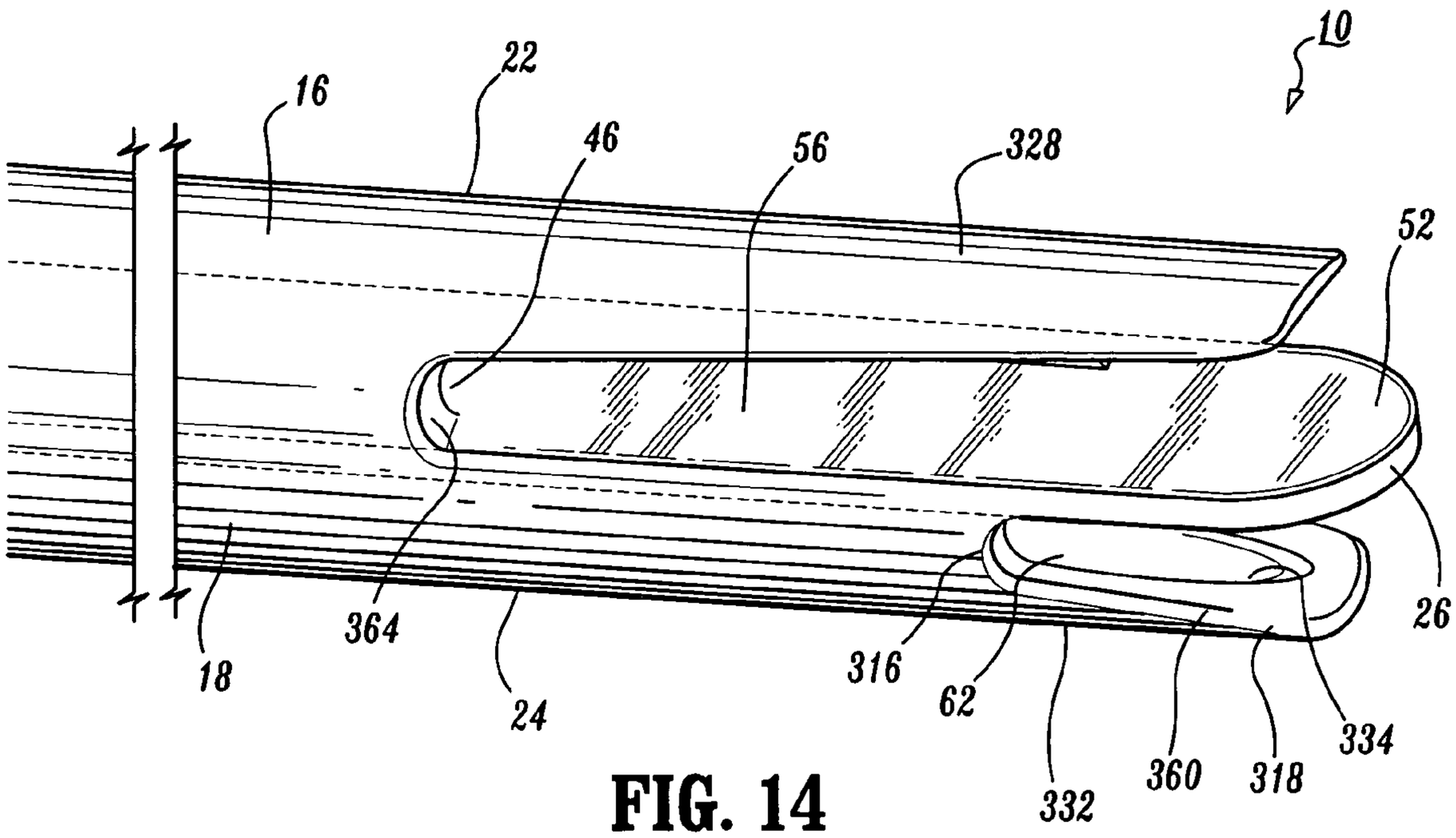
FIG. 13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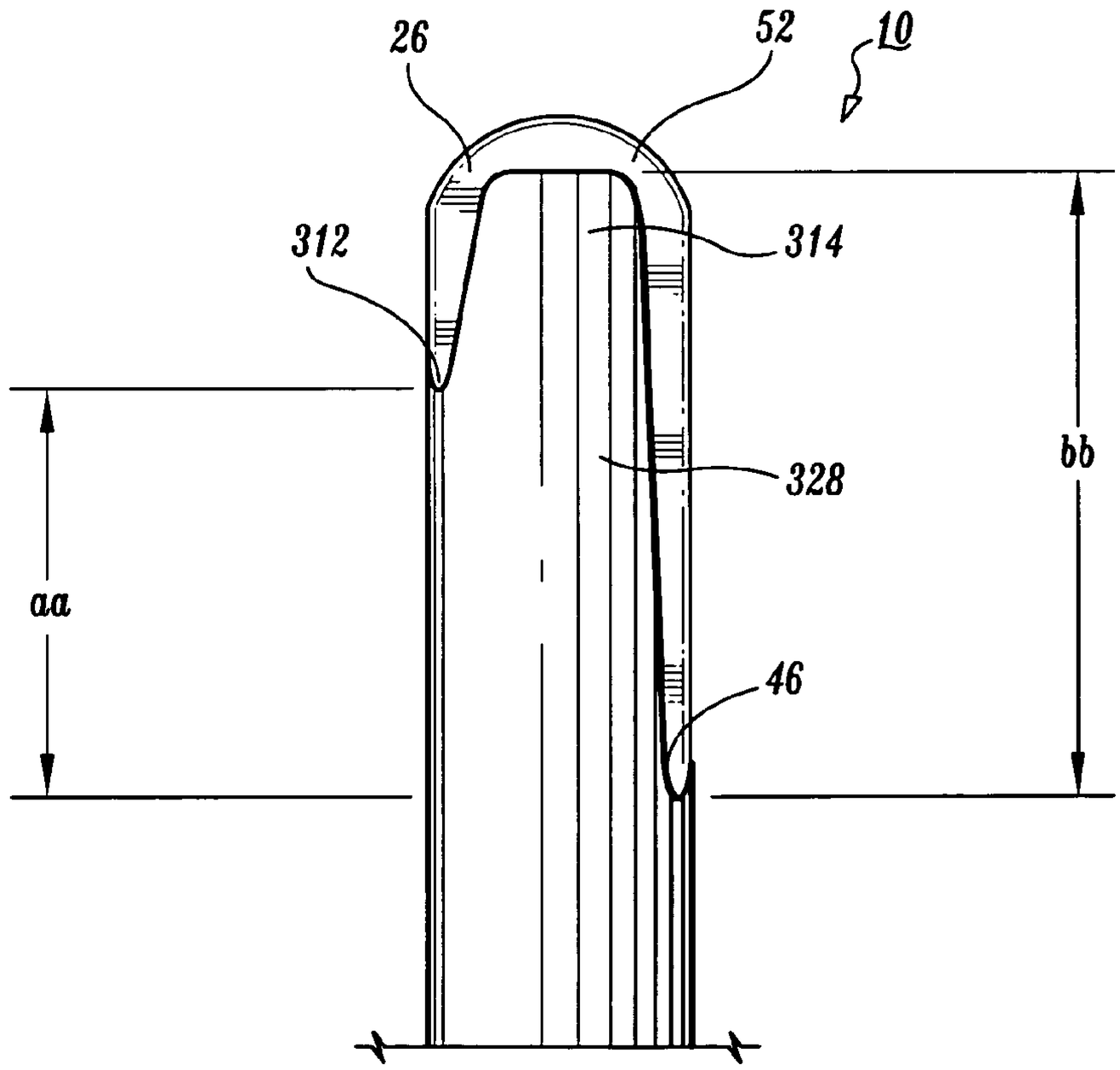
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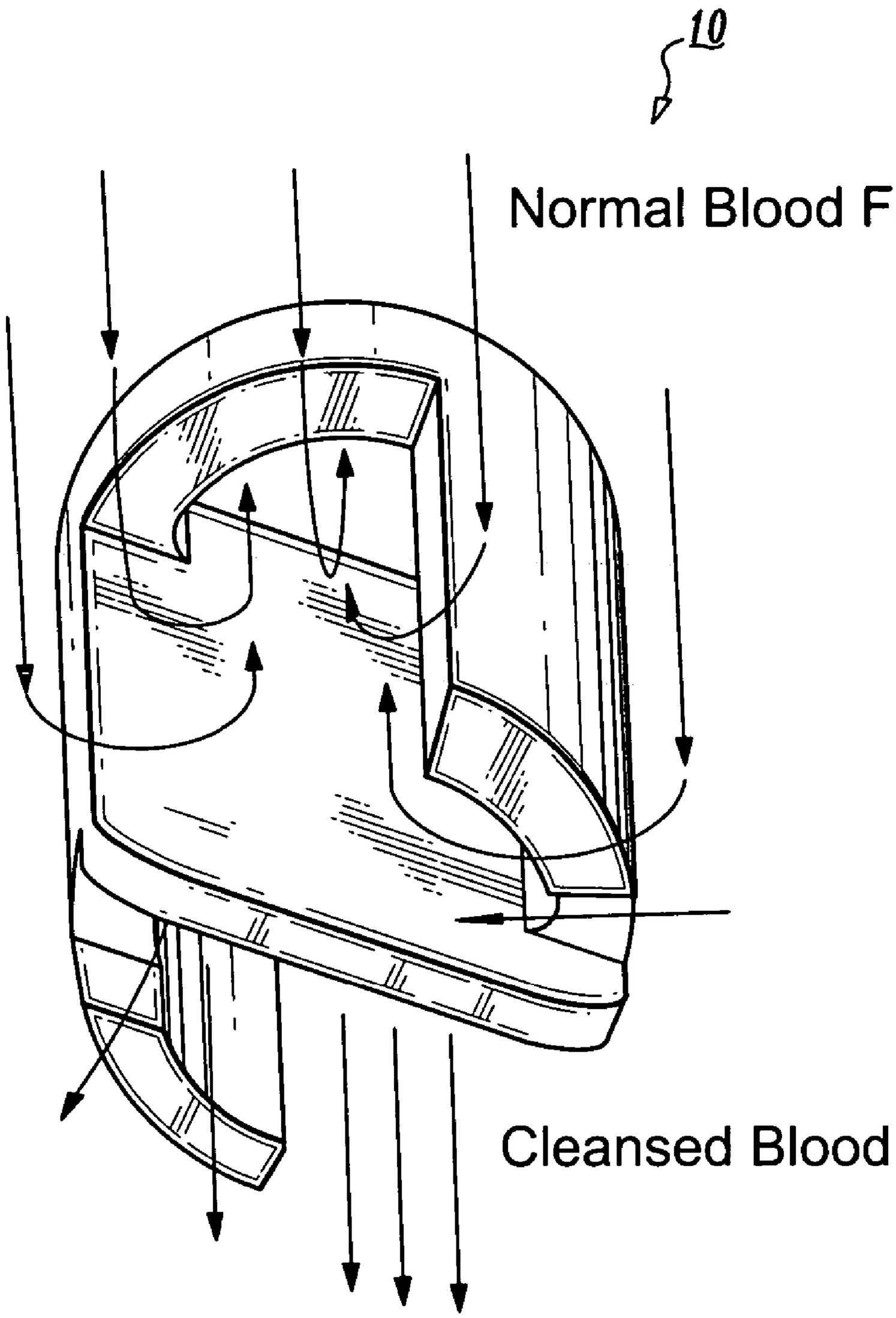
FIG. 15



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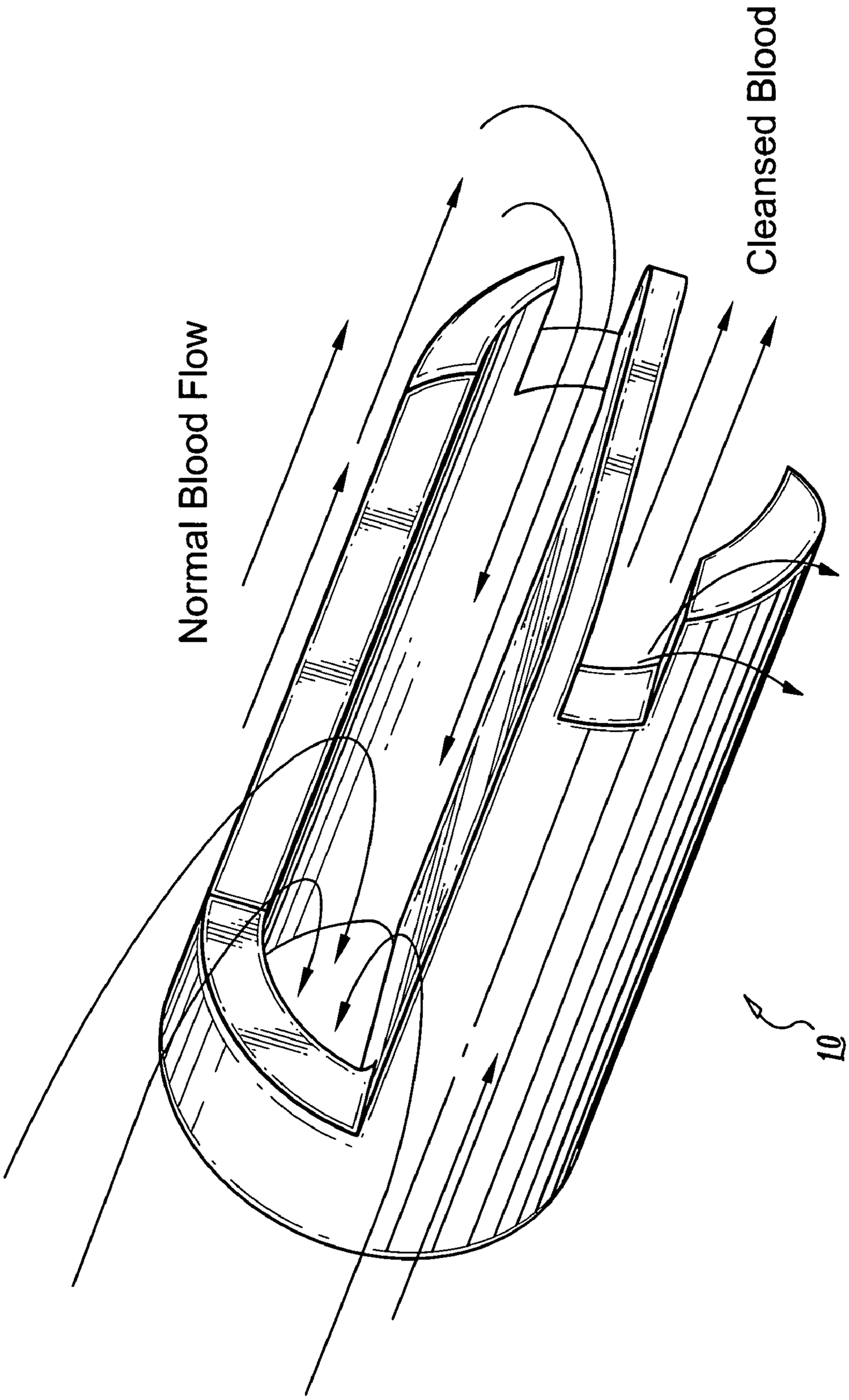
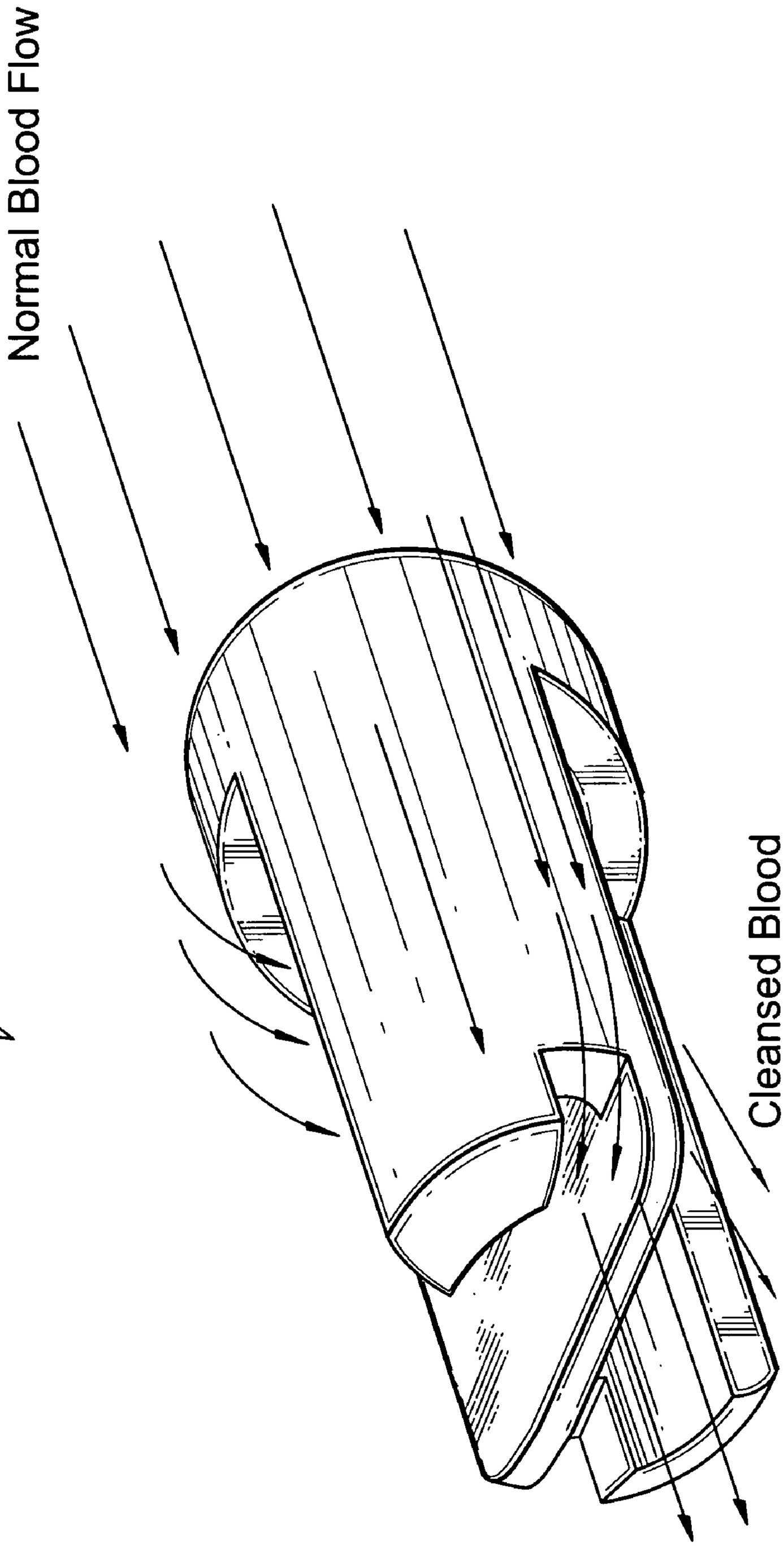


FIG. 17



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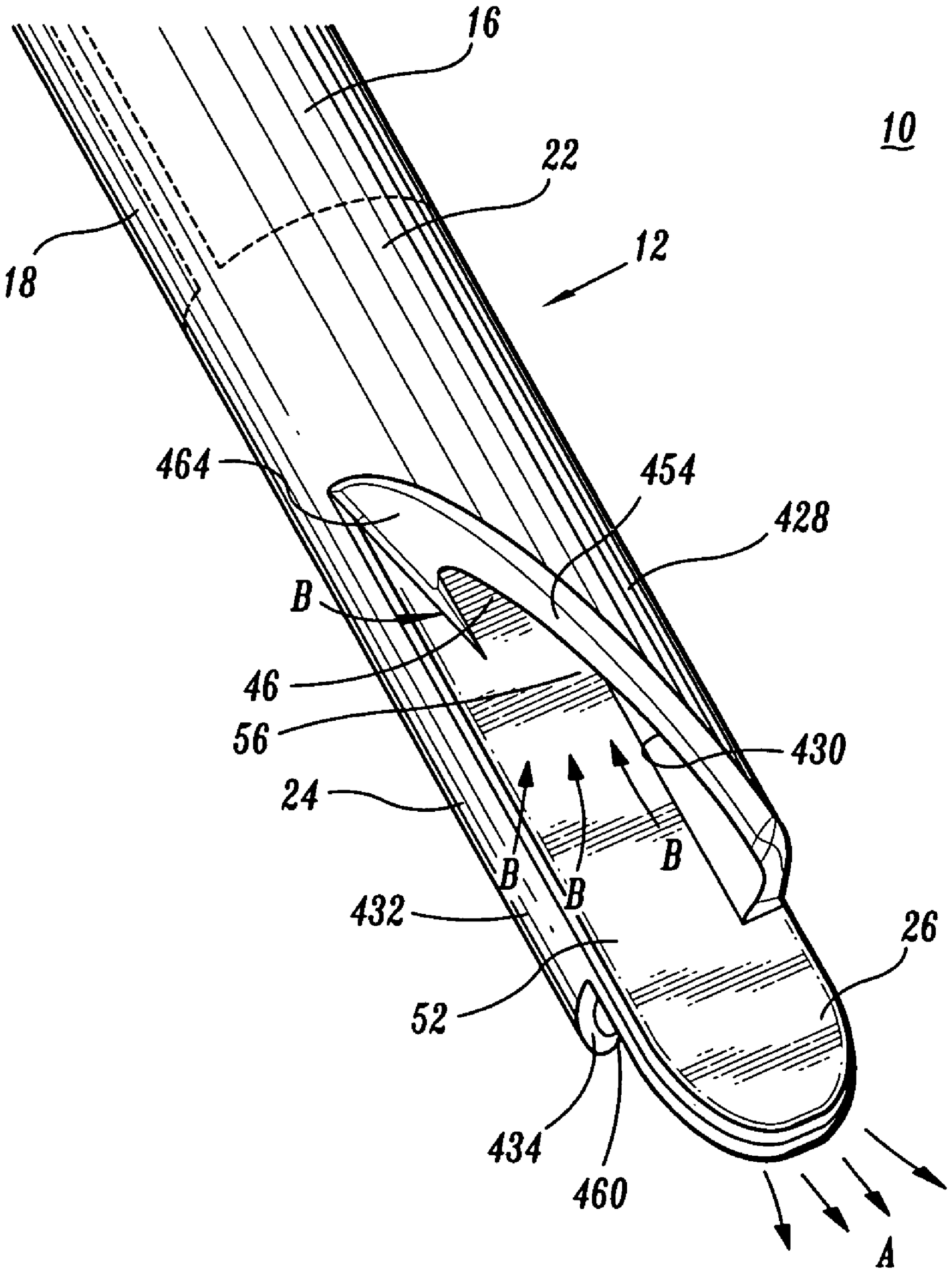

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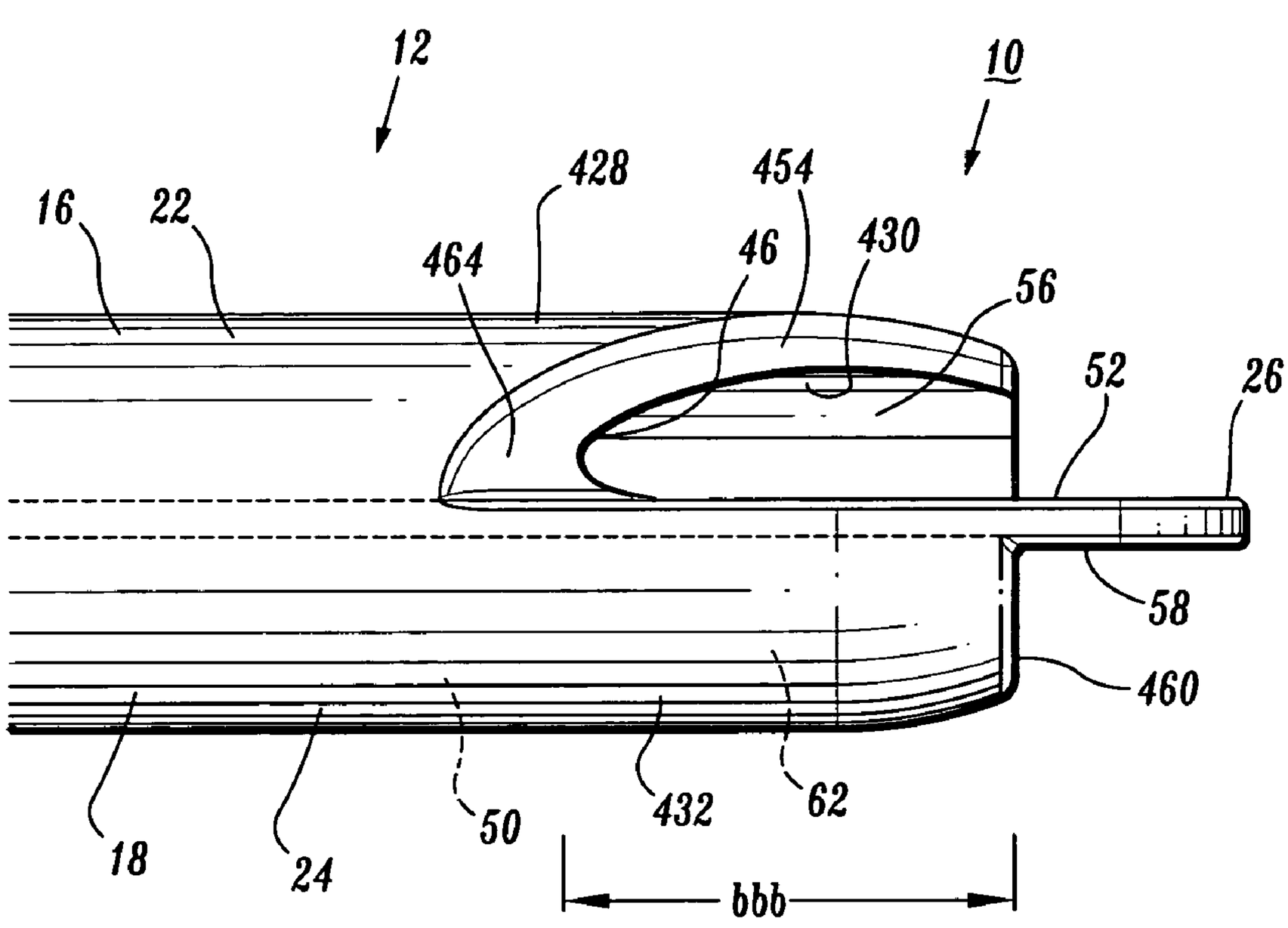

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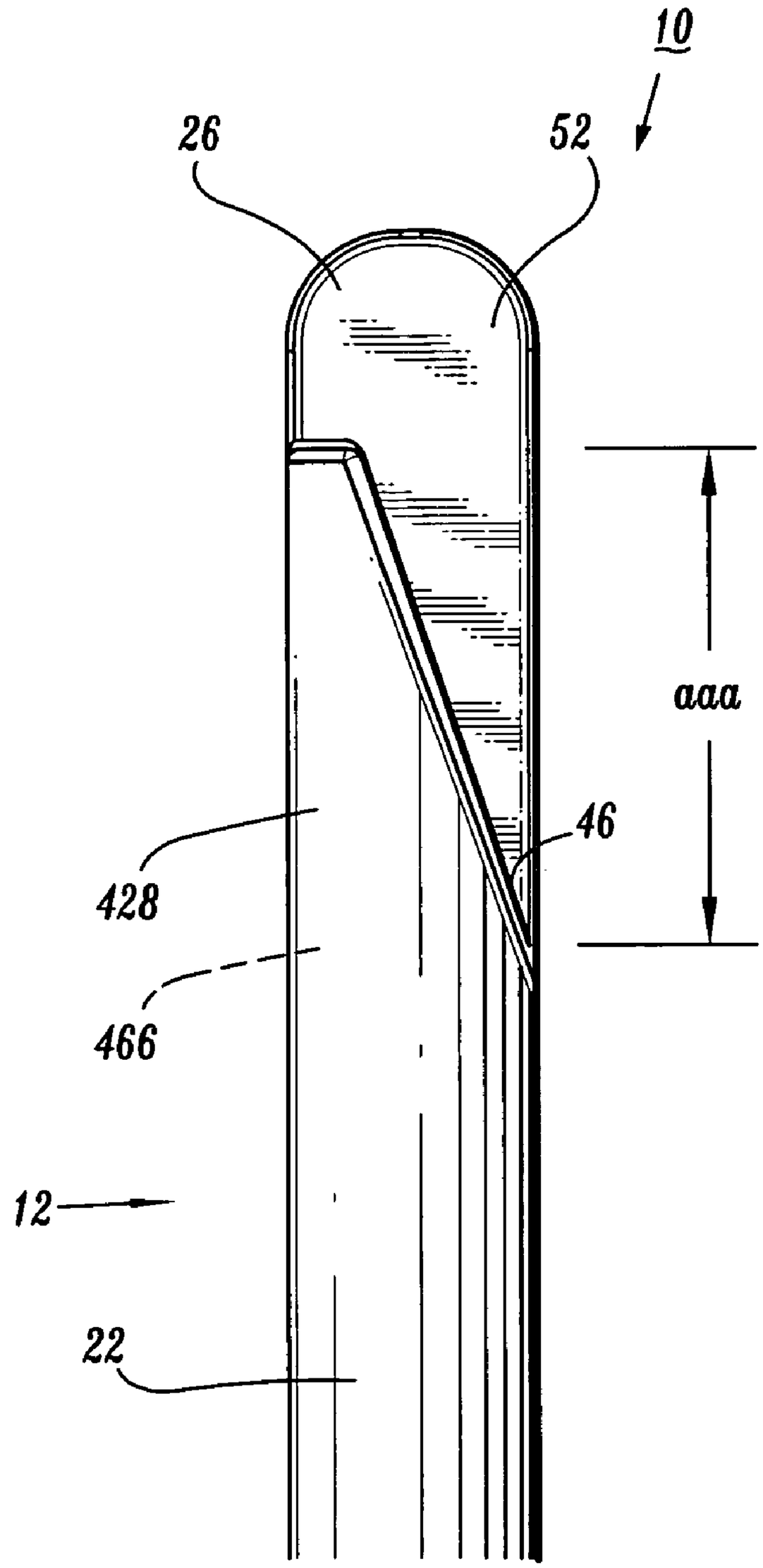

FIG. 21

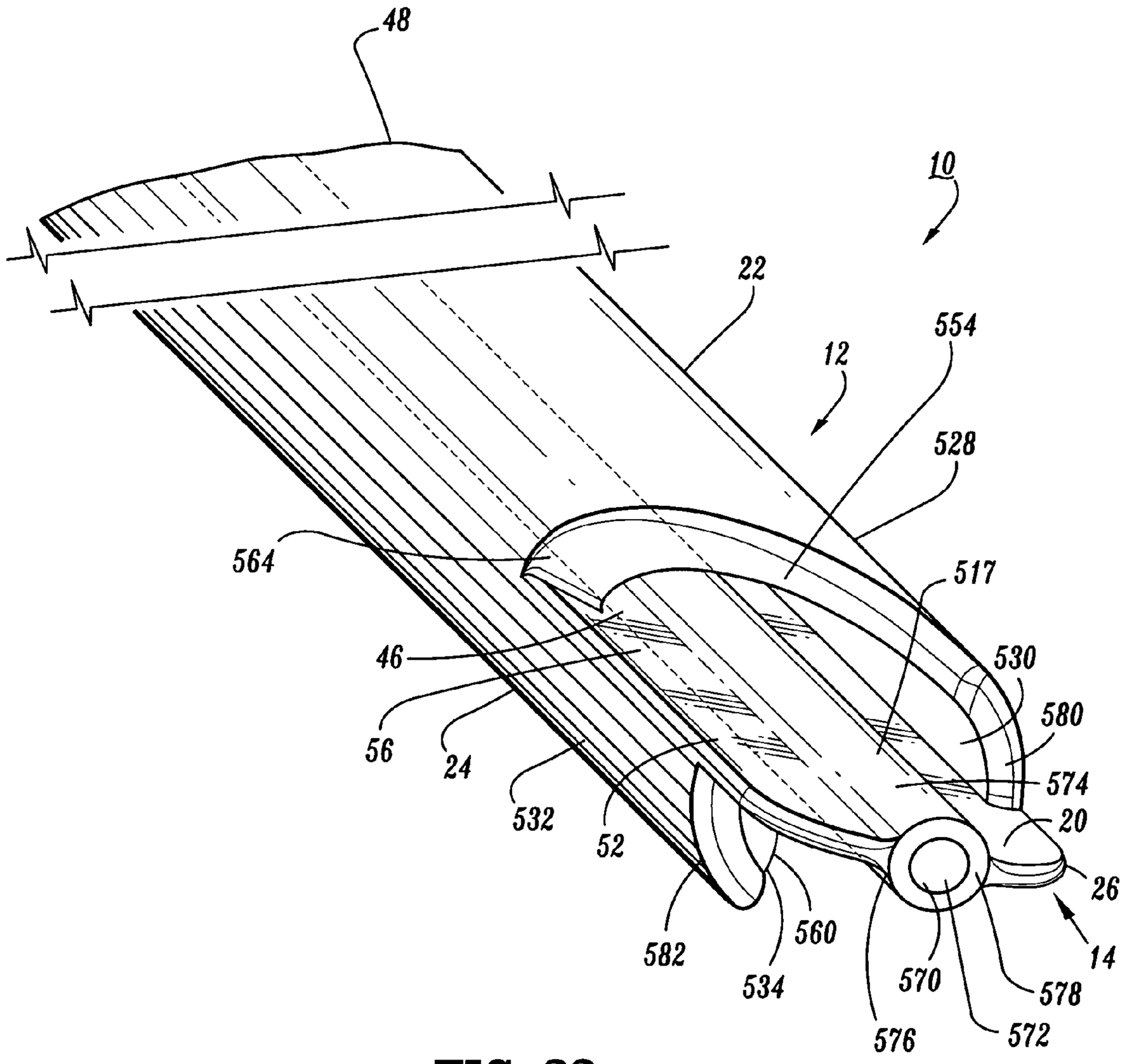
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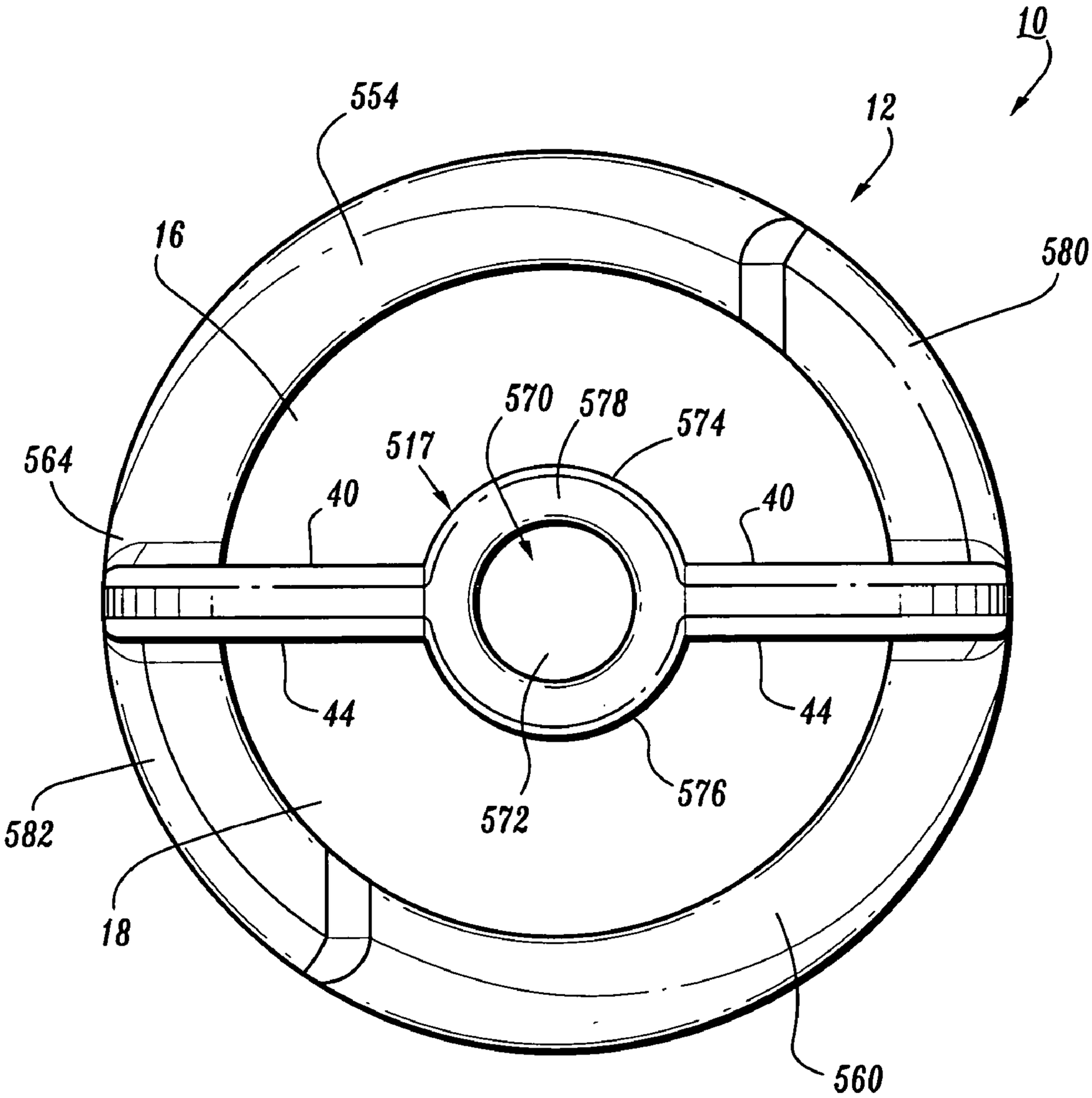
FIG. 22



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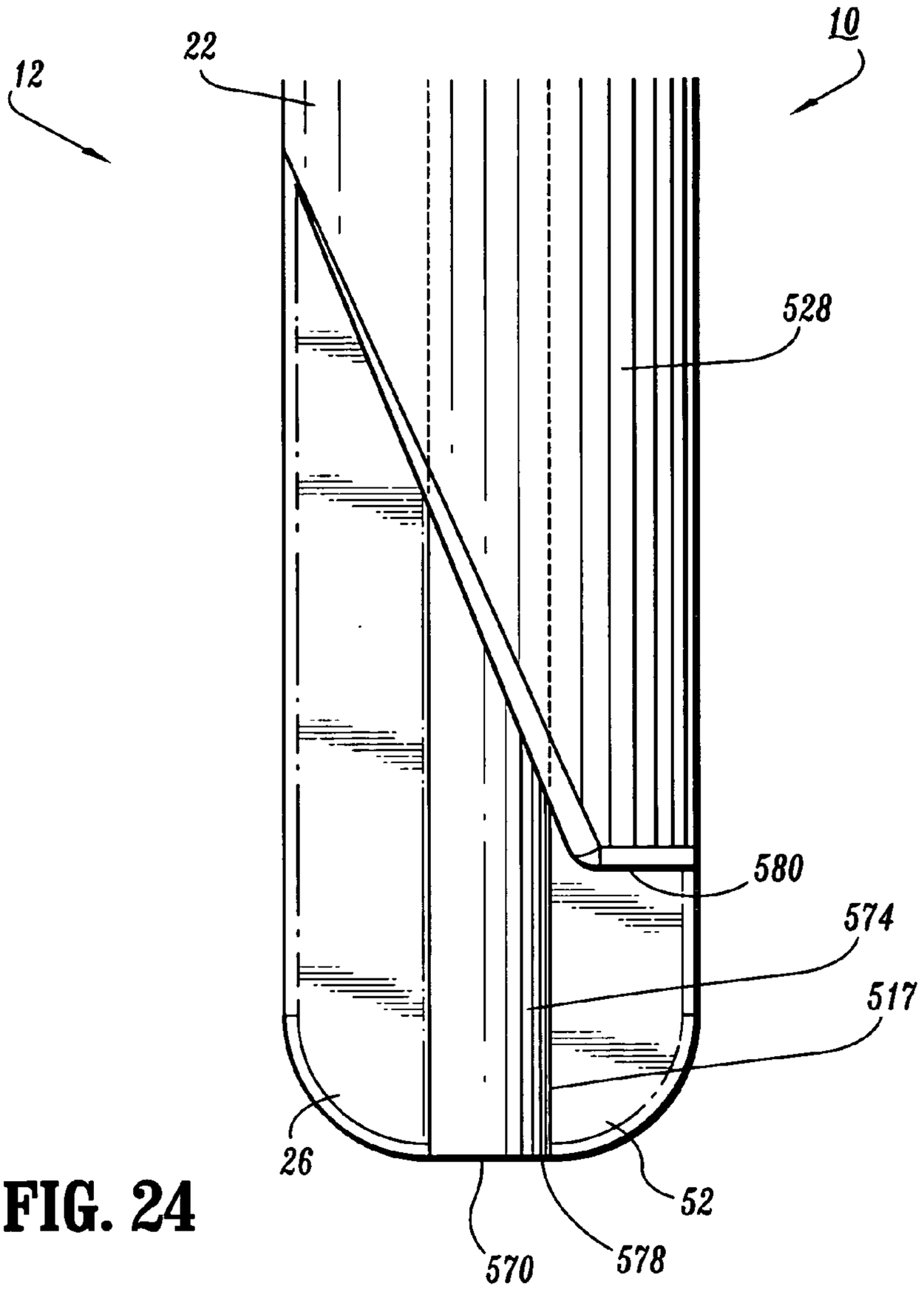
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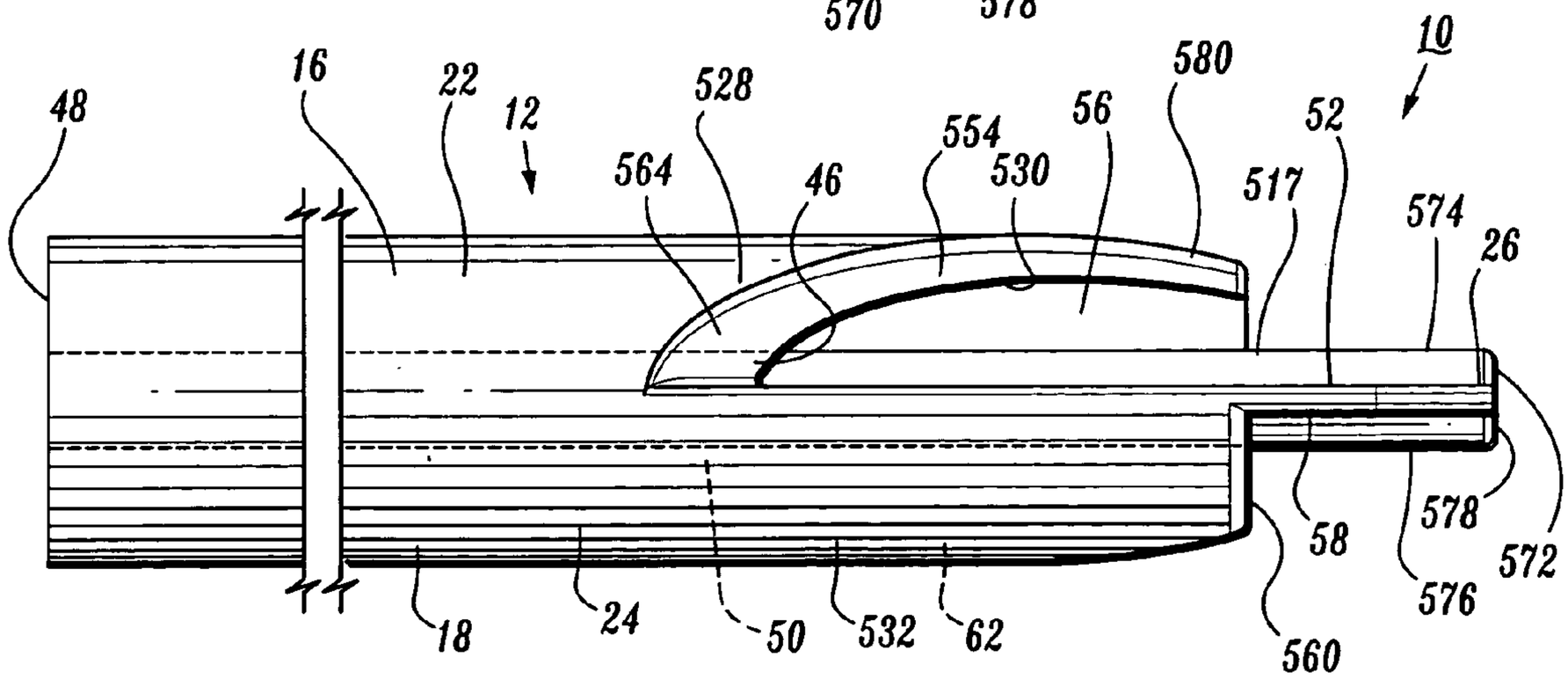
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FIG. 25

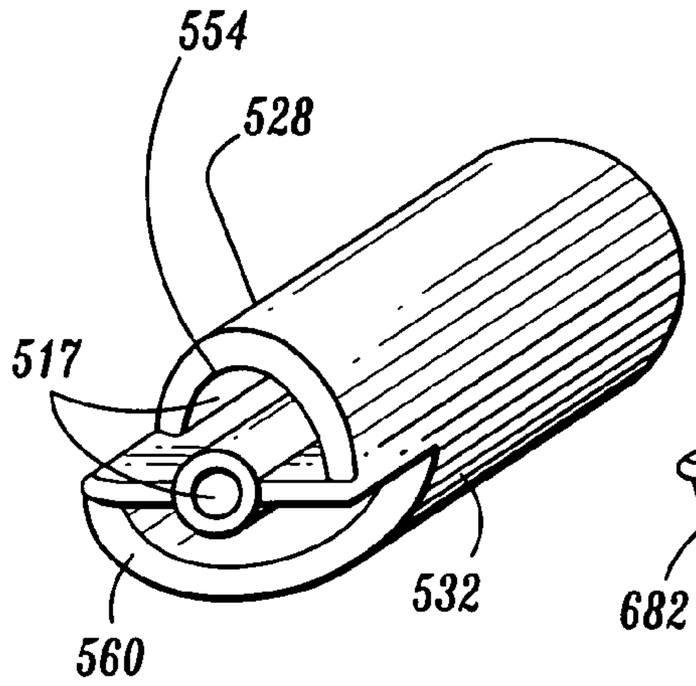


FIG. 26a

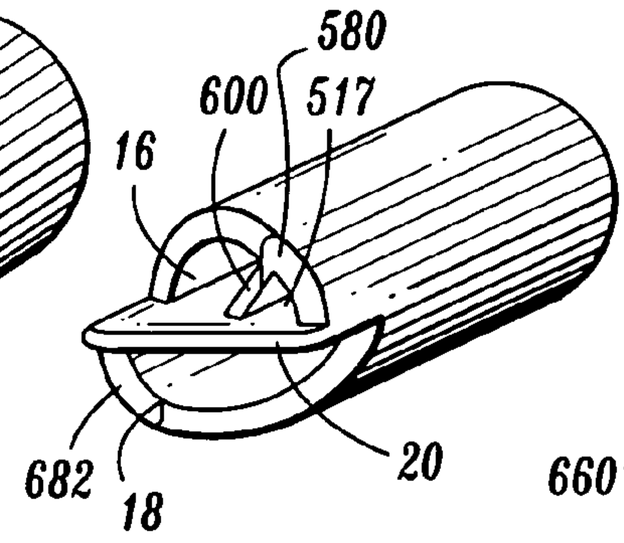
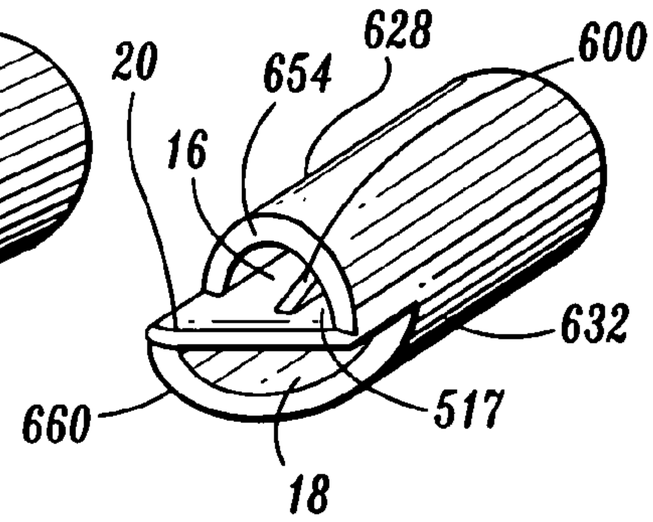


FIG. 26b



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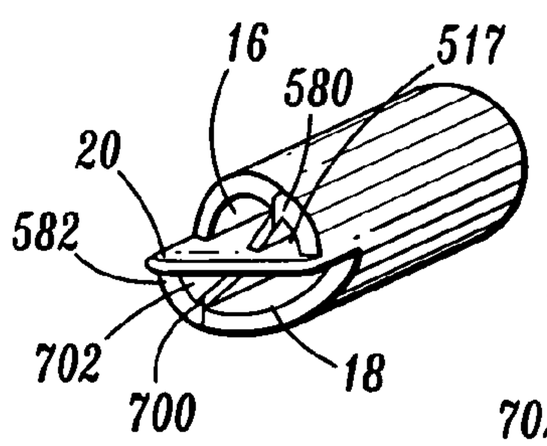

FIG. 26d

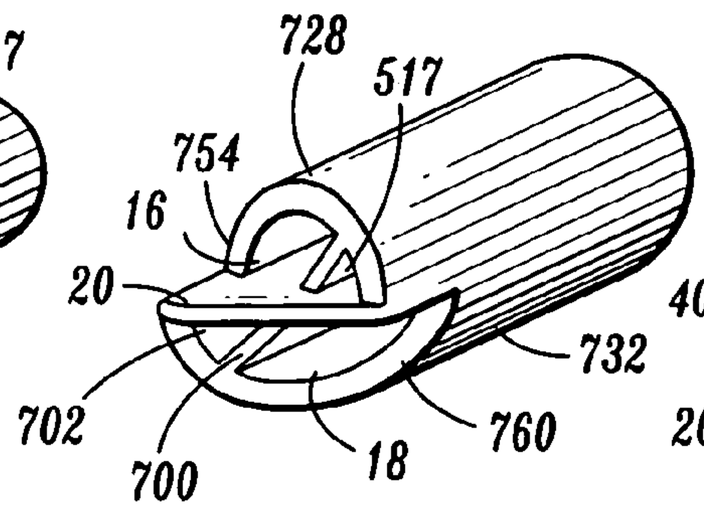

FIG. 26e

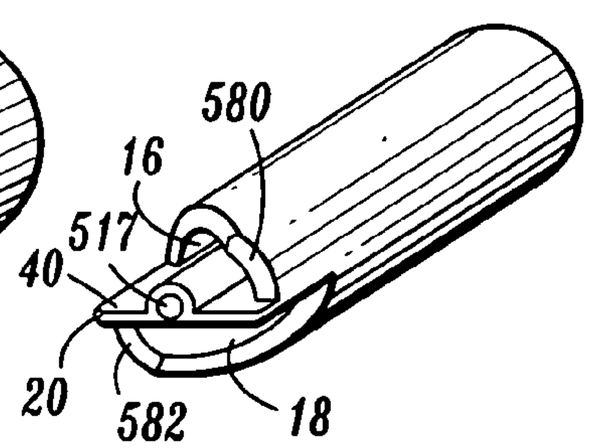

FIG. 26f

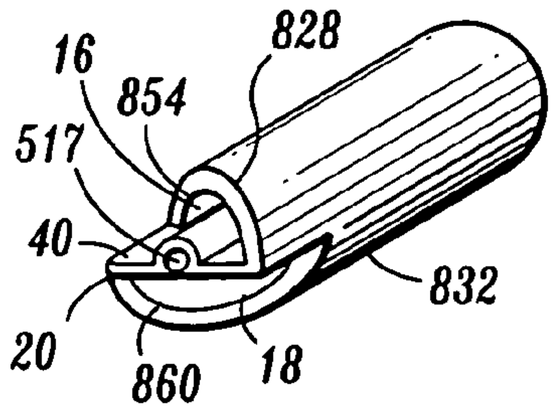

FIG. 26g

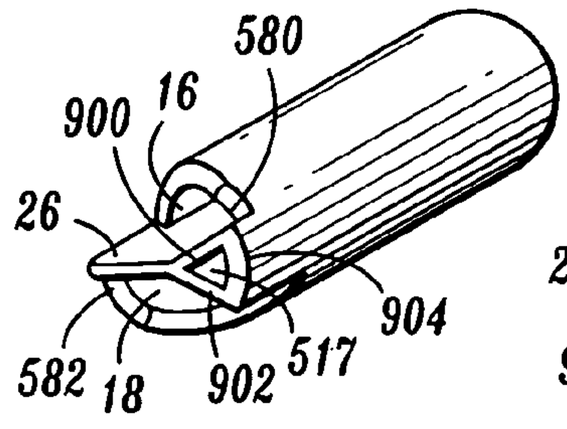

FIG. 26h

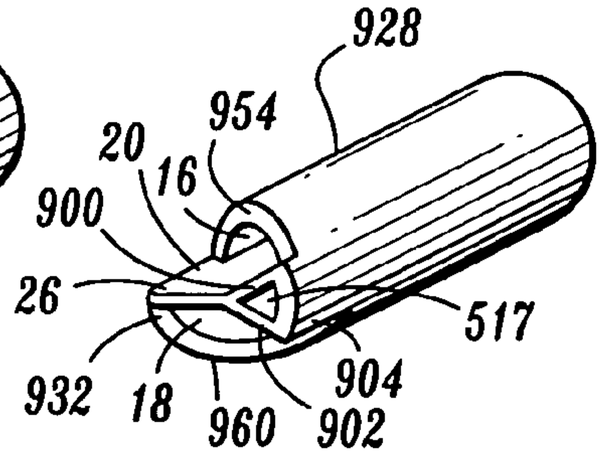

FIG. 26i

TRIPLE LUMEN CATHETER WITH OCCLUSION RESISTANT TIP

RELATED APPLICATION INFORMATION

This patent application is a continuation-in-part of U.S. patent application Ser. No. 10/602,897, filed on Jun. 24, 2003, now U.S. Pat. No. 7,141,035, which is a continuation-in-part of PCT International Application No. PCT/US03/09687, filed on Mar. 28, 2003 designating the United States of America, the entire contents of both being incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates generally to medical catheter apparatus, and more particularly to a multiple lumen catheter having a catheter tip that prevents occlusion during use.

2. Description of the Related Art

Some known catheters are tubular, flexible medical devices for administration of fluids (withdrawal, introduction, etc.) within cavities, ducts, vessels, etc. of a body.

These catheter devices may be employed for administration of fluids that includes the simultaneous introduction and withdrawal of fluid for applications such as, surgery, treatment, diagnosis, etc. In one particular hemodialysis application, blood is withdrawn from a blood vessel for treatment by an artificial kidney device and the treated blood is introduced back into the blood vessel.

Various known catheter devices have been employed for simultaneous withdrawal and introduction of fluid with a body. These devices may utilize multiple lumens, such as dual lumen catheters that facilitate bi-directional fluid flow whereby one lumen performs withdrawal of blood and the other lumen introduces treated blood to the vessel. During an exemplary hemodialysis procedure, a multiple lumen catheter is inserted into a body and blood is withdrawn through an arterial lumen of the catheter. This blood is supplied to a hemodialysis unit which dialyzes, or cleans, the blood to remove waste and excess water. The dialyzed blood is returned to the patient through a venous lumen of the catheter. Typically, the venous lumen is separated from the arterial lumen by an inner catheter wall, called a septum.

In addition, catheters can have a third lumen used, for example, in hemodialysis treatment of patients that require infusion of medication, blood sampling and/or pressure measurement in a vessel to control the infusion rate of intravenous fluids. Such catheters including at least three lumens facilitate simultaneous hemodialysis and other forms of fluid administration as described.

The efficiency of a hemodialysis procedure may be reduced by undesirable recirculation of blood flow whereby the dialyzed blood exiting the venous lumen is directly returned to the arterial lumen. To overcome this drawback some catheter devices stagger the openings of the lumens such that the opening of the venous lumen is disposed distally beyond the opening of the arterial lumen.

These catheter devices, however, also suffer from various additional drawbacks. For example, blood clots can form adjacent to or on the opening of both lumens and at locations between the openings of the lumens. Another drawback that may arise, due to the dedicated flow direction for a particular lumen, is recirculation if the flow direction is reversed. Further, suction introduced through lumen openings of the prior art may draw portions of a body vessel wall therein. These drawbacks can disadvantageously result in flow occlusion.

Therefore, it would be desirable to overcome the disadvantages and drawbacks of the prior art with a multiple lumen catheter including a catheter tip that prevents occlusion during use to facilitate unobstructed fluid flow. It would be desirable if such a catheter included concave surfaces adjacent the catheter tip to prevent occlusion and undesirable recirculation. The catheter may also facilitate reversible flow between lumens of the catheter. It would be highly desirable if the catheter and its constituent parts are easily and efficiently manufactured and assembled.

SUMMARY

Accordingly, a multiple lumen catheter is provided including a catheter tip that prevents occlusion during use to facilitate unobstructed fluid flow to overcome the disadvantages and drawbacks of the prior art. Desirably, such a catheter includes concave surfaces adjacent the catheter tip to prevent occlusion and undesirable recirculation. The catheter may also facilitate reversible flow between lumens of the catheter. Most desirably, the catheter is easily and efficiently manufactured and assembled. The present disclosure resolves related disadvantages and drawbacks experienced in the art.

The present disclosure provides, among other things, a multiple lumen dialysis catheter with a tip configuration such that the distal ends of the lumens terminate in symmetrical angled relationships. Distal wall extensions of the lumens are at the same longitudinal position along the catheter. The catheter may include sideholes.

Thus, the catheter tip configuration of the present disclosure advantageously reduces the potential for positional occlusion. The design of the catheter tip helps to keep the tip away from the sidewall of the vessel, eliminating the potential for the catheter to adhere to the vessel wall when suction is applied.

The symmetrical catheter tip design also advantageously facilitates the capability of bi-directional fluid flow for each lumen of the catheter. The symmetrical configuration of the catheter tip overcomes the disadvantages of dedicating a particular lumen to a flow direction, such as, for example, inflow, outflow, etc. This configuration results in similar recirculation in either direction of the blood flow (inflow lumen used for inflow and outflow lumen used for outflow, or outflow lumen used for inflow and inflow lumen used for outflow). Thus, blood clots attached to the catheter, including the septum may be washed away by alternating and/or reversing flow directions with consecutive dialysis. It is contemplated that the alternating and/or reversible flow may be provided by a source outside the body of the catheter such as, for example, a dialysis machine, etc. connected thereto.

In one particular embodiment, a catheter is provided, in accordance with the principles of the present disclosure. The catheter includes an elongated tubular body extending to a distal end thereof. The tubular body has a first lumen and a second lumen with a septum disposed therebetween. The tubular body includes a first wall that defines the first lumen and a second wall that defines the second lumen. A portion of the septum extending distally beyond the first lumen and the second lumen. The first wall includes a first wall extension that extends distally beyond the first lumen and is spaced apart from the portion of the septum. The first wall extension defines a concave surface facing the portion of the septum.

The portion of the septum may define a planar surface that faces the concave surface of the first wall extension. The first wall extension may include a planar end surface that forms a boundary about the concave surface of the first wall extension. The planar end surface can be disposed at an angular

orientation relative to a planar surface of the portion of the septum that faces the concave surface of the first wall extension.

Alternatively, the second wall includes a second wall extension that extends distally beyond the second lumen and is spaced apart from the portion of the septum. The second wall extension defines a concave surface facing the portion of the septum. The portion of the septum may define a planar surface that faces the concave surface of the second wall extension. The second wall extension may include a planar end surface that forms a boundary about the concave surface of the second wall extension. The planar end surface can be disposed at an angular orientation relative to a planar surface of the portion of the septum that faces the concave surface of the second wall extension.

The concave surface of the first wall extension may define a first cavity and the concave surface of the second wall extension may define a second cavity. The first cavity and the second cavity are symmetrical. The first wall extension and the second wall extension may be symmetrically disposed about the portion of the septum. The first wall extension may include a first step extending a first distance beyond the first lumen and a second step extending a second distance beyond the first lumen. The second wall extension may include a first step extending a first distance beyond the second lumen and a second step extending a second distance beyond the second lumen.

In an alternate embodiment, the septum has a septum extension disposed adjacent to a distal tip of the catheter and extends distally beyond the first lumen and the second lumen. The first wall extends distally beyond the first lumen and is spaced apart from the septum extension. The first wall extension defines a concave surface facing the septum extension. The second wall extends distally beyond the second lumen and is spaced apart from the septum extension. The second wall extension defines a concave surface facing the septum extension.

In another alternate embodiment, the septum extension defines a first planar surface and an opposing second planar surface. The first wall includes a first wall extension that extends distally beyond the first lumen and the second lumen. The first wall is spaced apart from the septum extension. The first wall extension defines a concave surface facing the first planar surface of the septum extension and is bounded by a planar end surface of the first wall extension. The planar end surface of the first wall extension is disposed at an angular orientation relative to the first planar surface of the septum extension. The second wall includes a second wall extension that extends distally beyond the first lumen and the second lumen. The second wall is spaced apart from the septum extension. The second wall extension defines a concave surface facing the second planar surface of the septum extension and is bounded by a planar end surface of the second wall extension. The planar end surface of the second wall extension is disposed at an angular orientation relative to the second planar surface of the septum extension.

In another alternate embodiment, the concave surface of the first wall extension defines a first cavity and the concave surface of the second wall extension defines a second cavity. The first wall extension includes a first base that defines an inlet opening of the first cavity. The first base is disposed proximal to fluid flow being expelled from the second cavity of the second wall extension. The second wall extension may include a second base that defines an inlet opening of the second cavity. The second base is disposed proximal to fluid flow being expelled from the first cavity of the second wall extension. The first base and/or the second base may have an arcuate configuration.

In another alternate embodiment, the first wall includes a first wall extension that extends in a spiral configuration from the first lumen and is spaced apart from the portion of the septum. The second wall may include a second wall extension that extends in a spiral configuration from the second lumen and is spaced apart from the portion of the septum. The first wall extension may include a planar end surface that forms a boundary about the first wall extension and defines the spiral configuration of the first wall extension. The second wall extension may include a planar end surface that forms a boundary about the second wall extension and defines the spiral configuration of the second wall extension.

In an alternate embodiment, the tubular body has a third lumen. The third lumen may be located coaxially along a longitudinal center axis of the body, and may extend beyond the first and second wall extensions having spiral configurations. The third lumen may have a circular cross section and its interior defined by an annular surface. The third lumen's exterior may be defined by a first outer wall and a second outer wall, with the third lumen separated from the first lumen by the first outer wall, and separated from the second lumen by the second outer wall. The third lumen's first outer wall may bound lengthwise by a first surface of the septum, and its second outer wall bound along the length of the third lumen by a second surface of the septum.

As described above, the present invention can provide a multiple lumen dialysis catheter with a tip configuration in which the distal ends of the lumens terminate in symmetrical angled relationships. The distal wall extensions of the lumens are at the same longitudinal position along the catheter. The catheter may include sideholes.

Accordingly, the catheter tip configuration advantageously reduces the potential for positional occlusion. The design of the catheter tip helps to keep the tip away from the sidewall of the vessel, eliminating the potential for the catheter to adhere to the vessel wall when suction is applied.

In addition, the symmetrical catheter tip design advantageously provides the capability of bi-directional fluid flow for each lumen of the catheter. The symmetrical configuration of the catheter tip overcomes the disadvantages of dedicating a particular lumen to a flow direction, such as, for example, inflow, outflow, etc. This configuration results in similar recirculation in either direction of the blood flow. Thus, blood clots attached to the catheter, including the septum, may be washed away by alternating flow directions with consecutive dialysis. Inclusion of a third lumen allows for infusion of fluids while the other two lumens are in use.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the present disclosure, which are believed to be novel, are set forth with particularity in the appended claims. The present disclosure, both as to its organization and manner of operation, together with further objectives and advantages, may be best understood by reference to the following description, taken in connection with the accompanying drawings, as set forth below.

FIG. **1** is a perspective view of a catheter in accordance with the principles of the present disclosure, showing a septum in phantom;

FIG. **2** is a side view of a distal end of the catheter shown in FIG. **1**;

FIG. **3** is a front view of the catheter shown in FIG. **1**;

FIG. **4** is an enlarged side view of the distal end of the catheter shown in FIG. **1**;

FIG. **5** is an enlarged side view of an alternate embodiment of the distal end of the catheter shown in FIG. **1**;

FIG. **6** is an enlarged perspective view of another alternate embodiment of the catheter shown in FIG. **1**;

FIG. **7** is an enlarged alternate perspective view of the catheter shown in FIG. **6**;

FIG. **8** is an enlarged alternate perspective view of the catheter shown in FIG. **6**;

FIG. **9** is an enlarged alternate perspective view of the catheter shown in FIG. **6**;

FIG. **10** is a perspective view of another alternate embodiment of the catheter shown in FIG. **1**;

FIG. **11** is a side view of the catheter shown in FIG. **10**;

FIG. **12** is an alternate perspective view of the catheter shown in FIG. **10**;

FIG. **13** is an alternate perspective view of the catheter shown in FIG. **10**;

FIG. **14** is an alternate perspective view of the catheter shown in FIG. **10**;

FIG. **15** is an alternate side view of the catheter shown in FIG. **10**;

FIG. **16** is a perspective view of the catheter shown in FIG. **10**, illustrating fluid flow;

FIG. **17** is a perspective view of the catheter shown in FIG. **10**, illustrating fluid flow;

FIG. **18** is a perspective side view of the catheter shown in FIG. **10**, illustrating fluid flow;

FIG. **19** is a perspective view of another alternate embodiment of the catheter shown in FIG. **1**;

FIG. **20** is a side view of the catheter shown in FIG. **19**;

FIG. **21** is an alternate side view of the catheter shown in FIG. **19**;

FIG. **22** is a perspective view of another alternate embodiment of the catheter shown in FIG. **1**;

FIG. **23** is a front view of the catheter shown in FIG. **22**;

FIG. **24** is a cutaway side view of a distal end of the catheter shown in FIG. **22**;

FIG. **25** is an alternate side view of the catheter shown in FIG. **22**; and

FIGS. **26***a*-**26***i* are perspective cutaway views of alternate configurations of a distal end of the catheter shown in FIG. **22**.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the catheter and methods of use disclosed are discussed in terms of medical catheters for the administration of fluids (withdrawal, introduction, etc.) with the body of a subject and more particularly, in terms of a catheter including a catheter tip that prevents occlusion during use to facilitate unobstructed fluid flow. The catheter is advantageously configured to facilitate reversible fluid flow between lumens thereof. It is envisioned that the present disclosure may be employed with a range of catheters, such as, for example, hemodialysis, peritoneal, infusion, PICC, CVC, port, etc. and catheter applications including surgical, diagnostic and related treatments of diseases, body ailments, etc. of a subject. It is further envisioned that the principles relating to the catheter disclosed include employment with various catheter related procedures, such as, for example, hemodialysis, cardiac, abdominal, urinary, intestinal, etc., in chronic, acute, etc. applications. It is contemplated that the catheter can be used for administration of fluids such as, for example, medication, saline, bodily fluids such as, blood, urine, etc. The catheter may also be used to monitor subject condition.

In the discussion that follows, the term "proximal" will refer to the portion of a structure that is closer to a practitioner, while the term "distal" will refer to the portion that is further from the practitioner. As used herein, the term "subject" refers to a human patient or other animal. According to the present disclosure, the term "practitioner" refers to a doctor, nurse or other care provider and may include support personnel.

The following discussion includes a description of the catheter, in accordance with the principles of the present disclosure. Reference will now be made in detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGS. **1-4**, a catheter **10** includes an elongated tubular body **12** that extends to a distal end **14**. Body **12** has a first lumen **16** and a second lumen **18**, with a septum **20** disposed therebetween. Body **12** includes a first wall **22** that defines first lumen **16** and a second wall **24** that defines second lumen **18**. A portion, such as, for example, septum extension **26** of septum **20** extends distally beyond first lumen **16** and second lumen **18**. Septum **20** is medially disposed, along a substantial portion of the longitudinal length of body **12**, between first lumen **16** and second lumen **18**. Septum **20** may be variously disposed with body **12**, such as, for example, angularly offset relative to extended portions of the first and second walls, etc.

First wall **22** includes a first wall extension **28** that extends distally beyond first lumen **16** and is spaced apart from septum extension **26**. First wall extension **28** defines a concave surface **30** that faces septum extension **26**. Second wall **24** includes a second wall extension **32** that extends distally beyond second lumen **18** and is spaced apart from septum extension **26**. Second wall extension **32** defines a concave surface **34** that faces septum extension **26**.

Septum extension **26** extends beyond first wall extension **28** and second wall extension **32**. Septum extension **26** is medially disposed, as extending from body **12**, between first wall extension **28** and second wall extension **32**. Septum extension **26** may be variously disposed for extension from body **12**. The disclosed configuration of catheter **10** advantageously prevents occlusion of first lumen **16** and second lumen **18**, as will be discussed. One or a plurality of wall extensions may be employed with catheter **10**, according to the particular requirements of a catheter application.

Body **12** has a cylindrical outer surface **36**. It is contemplated that body **12** may be variously dimensioned and attachable to other medical devices. It is further contemplated that outer surface **36** may have various cross-sectional configurations, such as, for example, oval, rectangular, elliptical, polygonal, etc. Body **12** may also include lateral openings. First wall **22** has a wall surface **38** that defines first lumen **16** in cooperation with a surface **40** of septum **20**. Second wall **24** has a wall surface **42** that defines second lumen **18** in cooperation with a surface **44** of septum **20**.

Lumens **16**, **18** each may have a substantially D-shaped or semi-circular configuration. Lumens **16**, **18** are elongated with body **12** and surfaces **38**, **40**, **42**, **44** are configured to facilitate fluid flow within lumens **16**, **18**. It is contemplated that lumens **16**, **18** may be configured for arterial and/or venous flow. It is envisioned that lumens **16**, **18** may have various configurations, such as, for example, cylindrical, rectangular, elliptical, polygonal, etc. The first and second

lumens may be configured for various forms of fluid flow in various directions and orientations, according to the requirements of a particular catheter application.

Lumens **16**, **18** may be uniformly dimensioned or include alternative dimensional cross sections within body **12**, such as, narrow and broad portions, converging surfaces, undulating surfaces, etc. according to the particular flow indications and/or flow rate requirements. It is contemplated lumen **16** and lumen **18** may extend alternative lengths. It is further contemplated that body **12** may include one or a plurality of lumens, such as, for example, a triple lumen configuration, etc.

First lumen **16** includes a first opening, such as, for example, an inlet opening **46** that is disposed adjacent to distal end **14** of body **12**. An outlet opening (not shown) of first lumen **16** is disposed adjacent a proximal end **48** of body **12**. Inlet opening **46** is configured for suction and may be inserted with a blood vessel of a subject (not shown) such that blood is withdrawn, by for example, arterial blood flow in a first direction, from the blood vessel for treatment by an artificial kidney device (not shown). Inlet opening **46** may be variously dimensioned and configured, such as, for example, rectangular, elliptical, polygonal, etc. and may include adapters, clips, etc. to facilitate fluid flow and/or attachment to other structure. It is contemplated that inlet opening **46** may be configured for expulsion of fluid.

First lumen **16** is separated from second lumen **18** by septum **20**. Second lumen **18** includes a second opening, such as, for example, an outlet opening **50** that is disposed adjacent to distal end **14** and in substantial longitudinal alignment, along body **12**, with inlet opening **46**. An inlet opening (not shown) of second lumen **18** is disposed adjacent proximal end **48**. Outlet opening **50** is configured for expulsion of fluid and introduces the treated blood from the artificial kidney device back into the blood vessel, by for example, venous blood flow in a second opposite direction. Outlet opening **50** may be variously dimensioned and configured, such as, for example, rectangular, elliptical, polygonal, etc. and may include adapters, clips, etc. to facilitate fluid flow and/or attachment to other structure. It is contemplated that outlet opening **50** may be configured for withdrawal of fluid.

The components of catheter **10** are fabricated from materials suitable for medical applications, such as, for example, polymerics or metals, such as stainless steel, depending on the particular catheter application and/or preference of a practitioner. Semi-rigid and rigid polymerics are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. One skilled in the art, however, will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

First wall extension **28** extends distally, a distance a, beyond inlet opening **46** of first lumen **16** and outlet opening **50** of second lumen **18**. It is contemplated that distance a may extend various lengths according to the requirements of a particular catheter application, such as, for example, approximately 0.100-0.200 inches. Concave surface **30** faces a first planar surface **52** of septum extension **26** and is spaced apart therefrom a distance b. It is contemplated that distance b may extend various lengths. It is further contemplated that surface **52** may be non-planar, such as, for example, arcuate, undulating, textured, etc.

Concave surface **30** is bounded by a planar end surface **54** of first wall extension **28** and spans a radial distance c. End surface **54** extends about the perimeter of concave surface **30** such that first wall extension **28** has a scoop-like configuration that facilitates fluid flow through first lumen **16**. It is contemplated that first wall extension **28** may form alternate configurations, such as, for example, spherical, rectangular, etc. End surface **54** includes a radial portion **55** adjacent a distal end of first wall extension **28**. Radial portion **55** extends to the longitudinally oriented outer surface **36** of body **12** in an arcuate configuration. This configuration advantageously prevents a vessel wall (not shown) from becoming disposed within the inlet of first lumen **16**. In an alternate embodiment, as shown in FIG. **5**, a radial portion **155** extends to the longitudinally oriented outer surface **36** of body **12** in a perpendicular convergence.

It is contemplated that distance c may extend various lengths. Planar end surface **54** is disposed at an angular orientation a relative to first planar surface **52**. It is envisioned that end surface **54** may be disposed at various angular orientations a, such as, for example, 5-20 degrees.

Concave surface **30** and first planar surface **52** cooperate to define a first cavity **56**. First cavity **56** is disposed distally beyond inlet opening **46**. First cavity **56** is dimensioned and configured according to the bounds of one or all of inlet opening **46**, concave surface **30**, planar end surface **54** and septum extension **26**, according to the particular requirements of a catheter application. The extension of first cavity **56** distally beyond inlet opening **46** prevents undesirable recirculation of fluid flow between first lumen **16** and second lumen **18** as facilitated by the barrier provided by septum extension **26**.

Second wall extension **32** extends distally, a distance d, beyond outlet opening **50** of second lumen **18** and inlet opening **46** of first lumen **16**. It is contemplated that distance d may extend various lengths according to the requirements of a particular catheter application, such as, for example, approximately 0.100-0.200 inches. Concave surface **34** faces a second planar surface **58** of septum extension **26**, opposing first planar surface **52**, and is spaced apart therefrom a distance e.

It is contemplated that distance e may extend various lengths. It is further contemplated that surface **58** may be non-planar, such as, for example, arcuate, undulating, textured, etc. It is envisioned that surface **52** may be disposed at angular orientations relative to surface **58**.

Concave surface **34** is bounded by a planar end surface **60** of second wall extension **32** and spans a radial distance f. End surface **60** extends about the perimeter of concave surface **34** such that second wall extension **32** has a scoop-like configuration that facilitates fluid flow through second lumen **18**. It is envisioned that second wall extension **32** may form alternate configurations, such as, for example, spherical, rectangular, etc. End surface **60** includes a radial portion **61** adjacent a distal end of second wall extension **32**. Radial portion **61** extends to the longitudinally oriented outer surface **36** of body **12** in an arcuate configuration. This configuration advantageously prevents, for example, a vessel wall (not shown) from becoming disposed within the distal opening of second lumen **18** in the event fluid is reversed and suction is provided for withdrawal of fluid therethrough. In an alternate embodiment, as shown in FIG. **5**, a radial portion **161** extends to the longitudinally oriented outer surface **36** in a perpendicular intersection.

It is contemplated that distance f may extend various lengths. Planar end surface **60** is disposed at an angular orientation β relative to second planar surface **58**. It is envisioned that end surface **60** may be disposed at various orientations β, such as, for example, 5-20 degrees.

Concave surface **34** and second planar surface **58** cooperate to define a second cavity **62**. Second cavity **62** is disposed distally beyond outlet opening **50**. Second cavity **62** is dimensioned and configured according to the bounds of one or all of

outlet opening **50**, concave surface **34**, planar end surface **60** and septum extension **26**, according to the particular requirements of a catheter application. The extension of second cavity **62** distally beyond outlet opening **50** prevents undesirable recirculation of fluid flow between second lumen **18** and first lumen **16** as facilitated by the barrier provided by septum extension **26**.

First wall extension **28** and second wall extension **32** are symmetrically disposed about septum extension **26** such that first cavity **56** and second cavity **62** are symmetrical. First cavity **56** and second cavity **62** bound an equivalent space to facilitate inflow and outflow capability for each lumen. The space bounded by first cavity **56** and second cavity **62** have an angular orientation as facilitated by respective planar end surfaces **54**, **60**, discussed above. The angular orientations of planar end surfaces **54**, **60** (α, β) cause cavities **56**, **62** to direct fluid in the direction shown by the arrows in FIG. **4**.

The configuration of catheter **10** advantageously facilitates reversible flow between first lumen **16** and second lumen **18** such that, for example, blood clots attaching to catheter **10**, including septum **20**, may be washed away by alternating blood flow directions. As second lumen **18** expels blood flow for introduction to the body vessel, blood flow is forced out of second lumen **18**. The blood flow is axially directed out of cavity **62** past second wall extension **32**. It is envisioned that such axially directed blood flow washes away any blood clots disposed adjacent cavity **62**. It is further envisioned that fluid flow exiting second lumen **18** may wash other particles undesirably attached to catheter **10**. This configuration prevents undesirable recirculation of fluid flow between second lumen **18** and first lumen **16**. Thus, blood clots, etc. attached to catheter **10**, including septum **20** may be washed away by alternating and/or reversing flow directions with consecutive dialysis. It is contemplated that the alternating and/or reversible flow may be provided by a source outside the body of catheter **10** such as, for example, a dialysis machine, etc. connected thereto.

First lumen **16** is provided with suction to withdraw fluids from the body vessel. Efficiency of fluid inflow through cavity **56** to first lumen **16** is improved due to the configuration of cavity **56** and consequent fluid direction. It is contemplated that blood clots, or other undesired particles, disposed adjacent cavity **56** of first lumen **16** may be washed away by reversing blood flow direction of lumens **16**, **18** with consecutive dialysis procedures. Upon reversal of blood flow direction, blood flow is expelled from cavity **56** and the axially directed blood flow washes away blood clots, similar to that described above. Second lumen **18** is provided with suction to withdraw fluids from the body vessel and into opening **50**.

The symmetrical configuration of first wall extension **28** and second wall extension **32** supports a vessel wall of a body vessel (not shown). This configuration spaces the vessel wall from inlet opening **46** and outlet opening **50** to prevent vessel wall occlusion of openings **46**, **50** during for example, suction through the lumens. It is further envisioned that first wall extension **28** and second wall extension **32** may have sufficient thickness and/or be fabricated from semi-rigid or rigid materials to prevent undesired deformation thereof.

Referring to FIGS. **6-9**, another alternate embodiment of catheter **10** is shown, similar to that described above. First wall **22** includes a first wall extension **228** that extends distally beyond first lumen **16** and is spaced apart from septum extension **26**. First wall extension **228** defines a concave surface **230** that faces septum extension **26**. Second wall **24** includes a second wall extension **232** that extends distally beyond second lumen **18** and is spaced apart from septum extension **26**. Second wall extension **32** defines a concave surface **234** that faces septum extension **26**.

First wall extension **228** includes a first step **212** and a second step **214** formed therewith. First step **212** is formed with septum extension **26**. First step **212** and second step **214** are circumferentially disposed about septum extension **26**. It is envisioned that first step **212** and/or second step **214** may have alternate configurations, such as, for example, planar, etc.

First step **212** extends distally, a distance aa, beyond inlet opening **46** of first lumen **16** and outlet opening **50** of second lumen **18**. Second step **214** extends distally a distance bb, beyond inlet opening **46** and outlet opening **50**. It is contemplated that distance aa and bb may extend various lengths. Concave surface **230** faces first planar surface **52** of septum extension **26** and is spaced apart therefrom. Concave surface **230** spans across approximately one-quarter of the circumference of body **12** or a substantially 90° arc as extended from septum extension **26**. It is envisioned that first step **212** and/or second step **214**, or other portions of concave surface **230** may be variously disposed about body **12**.

Concave surface **230** is bounded by a planar end surface **254** of first wall extension **228**. End surface **254** extends about the perimeter of concave surface **230** to facilitate fluid flow through first lumen **16**. Concave surface **230** and first planar surface **52** cooperate to define first cavity **56**, similar to that described above. First cavity **56** is further bounded by a proximal base **264**. Proximal base **264** defines a proximal inlet portion for first lumen **16** during withdrawal of fluids. It is contemplated that suction provided with first lumen **16** has a greater fluid flow rate adjacent proximal base **264**.

Second wall extension **232** includes a first step **216** and a second step **218** formed therewith. First step **216** is formed with septum extension **26**. First step **216** and second step **218** are circumferentially disposed about septum extension **26**. It is contemplated that first step **216** and/or second step **218** may have alternate configurations, such as, for example, planar, etc.

First step **216** extends distally, a distance dd, beyond outlet opening **50** and inlet opening **46**. Second step **218** extends distally a distance ee, beyond inlet opening **46** and outlet opening **50**. It is contemplated that distances dd and ee may extend various lengths. Concave surface **234** faces second planar surface **58** of septum extension **26**, opposing first planar surface **52**, and is spaced apart therefrom. Concave surface **234** spans across approximately one-quarter of the circumference of body **12** or a substantially 90° arc, as extended from septum extension **26**. It is envisioned that first step **216** and/or second step **218**, or other portions of concave surface **234** may be variously disposed about body **12**.

Concave surface **234** is bounded by a planar end surface **260** of second wall extension **232**. End surface **260** extends about the perimeter of concave surface **234** to facilitate fluid flow through second lumen **18**. Concave surface **234** and second planar surface **58** cooperate to define second cavity **62**, similar to that described above. Second cavity **62** is further bounded by a proximal base **266**. For example, if fluid flow is reversed with catheter **10**, proximal base **266** defines a proximal inlet portion for second lumen **18** during withdrawal of fluids. It is contemplated that suction provided with second lumen **18** has a greater fluid flow rate adjacent proximal base **266**.

First wall extension **228** and second wall extension **232** are symmetrically disposed about septum extension **26** such that first cavity **56** and second cavity **62** are symmetrical. First cavity **56** and second cavity **62** bound an equivalent space to facilitate inflow and outflow capability for each lumen.

The configuration of catheter **10** advantageously facilitates reversible flow between first lumen **16** and second lumen **18** such that, for example, blood clots attaching to catheter **10** may be washed away by alternating blood flow directions. As second lumen **18** expels blood flow for introduction to the body vessel, blood flow is forced out of second lumen **18**. The blood flow is axially directed out of cavity **62** past second wall extension **232**. It is envisioned that such axially directed blood flow washes away any blood clots disposed adjacent cavity **62**. It is further envisioned that fluid flow exiting second lumen **18** may wash other particles undesirably attached to catheter **10**.

First lumen **16** is provided with suction to withdraw fluids from the body vessel. The suction draws blood flow from various directions and orientations into inlet opening **46**. Suction is greater adjacent proximal base **264** due to its closer proximity to a suction source (not shown). Fluid flow is greater adjacent to proximal base **264** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **62** of second lumen **18**. This configuration minimizes recirculation between lumens **16**, **18**.

It is contemplated that blood clots, or other undesired particles, disposed adjacent cavity **56** of first lumen **16** may be washed away by reversing blood flow direction of lumens **16**, **18**. Upon reversal of blood flow direction, blood flow is expelled from cavity **56** and the axially directed blood flow washes away blood clots, similar to that described above.

Second lumen **18** is provided with suction to withdraw fluids from the body vessel and into opening **50**. Second wall extension **232** is symmetrical with first wall extension **228**, and therefore, similar to proximal base **264**, suction is greater adjacent proximal base **266**. Fluid flow is greater adjacent to proximal base **266** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **56**. This configuration minimizes recirculation between lumens **16**, **18**.

Referring to FIGS. **10-18**, another alternate embodiment of catheter **10** is shown, similar to that described above. First wall **22** includes a first wall extension **328** that extends distally beyond first lumen **16** and is spaced apart from septum extension **26**. First wall extension **328** defines a concave surface **330** that faces septum extension **26**. Second wall **24** includes a second wall extension **332** that extends distally beyond second lumen **18** and is spaced apart from septum extension **26**. Second wall extension **32** defines a concave surface **334** that faces septum extension **26**.

First wall extension **328** includes a first step **312** and a second step **314** formed therewith in an arcuate transition. First step **312** is formed with septum extension **26** in an arcuate transition. First step **312** and second step **314** are circumferentially disposed about septum extension **26**. It is envisioned that first step **312** and/or second step **314** may have alternate configurations, such as, for example, planar, etc.

First step **312** extends distally, a distance aa, beyond inlet opening **46** of first lumen **16** and outlet opening **50** of second lumen **18**. Second step **314** extends distally a distance bb, beyond inlet opening **46** and outlet opening **50**. It is contemplated that distance aa and bb may extend various lengths. Concave surface **330** faces first planar surface **52** of septum extension **26** and is spaced apart therefrom. Concave surface **330** spans across approximately one-quarter of the circumference of body **12** or a substantially 90° arc as extended from septum extension **26**. It is envisioned that first step **312** and/or second step **314**, or other portions of concave surface **330** may be variously disposed about body **12**.

Concave surface **330** is bounded by a planar end surface **354** of first wall extension **328**. End surface **354** extends about the perimeter of concave surface **330** to facilitate fluid flow through first lumen **16**. Concave surface **330** and first planar surface **52** cooperate to define first cavity **56**, similar to that described above. First cavity **56** is further bounded by a proximal base **364**. Proximal base **364** has an arcuate configuration and defines a proximal inlet portion for first lumen **16** during withdrawal of fluids. It is contemplated that suction provided with first lumen **16** has a greater fluid flow rate adjacent proximal base **364**.

Second wall extension **332** includes a first step **316** and a second step **318** formed therewith in an arcuate transition. First step **316** is formed with septum extension **26**. First step **316** and second step **318** are circumferentially disposed about septum extension **26**. It is contemplated that first step **316** and/or second step **318** may have alternate configurations, such as, for example, planar, etc.

First step **316** extends distally, a distance dd, beyond outlet opening **50** and inlet opening **46**. Second step **318** extends distally a distance ee, beyond inlet opening **46** and outlet opening **50**. It is contemplated that distances dd and ee may extend various lengths. Concave surface **334** faces second planar surface **58** of septum extension **26**, opposing first planar surface **52**, and is spaced apart therefrom. Concave surface **334** spans across approximately one-quarter of the circumference of body **12** or a substantially 90° arc, as extended from septum extension **26**. It is envisioned that first step **316** and/or second step **318**, or other portions of concave surface **334** may be variously disposed about body **12**.

Concave surface **334** is bounded by a planar end surface **360** of second wall extension **332**. End surface **360** extends about the perimeter of concave surface **334** to facilitate fluid flow through second lumen **18**. Concave surface **334** and second planar surface **58** cooperate to define second cavity **62**, similar to that described above. Second cavity **62** is further bounded by a proximal base **366**. For example, if fluid flow is reversed with catheter **10**, proximal base **366** has an arcuate configuration and defines a proximal inlet portion for second lumen **18** during withdrawal of fluids. It is contemplated that suction provided with second lumen **18** has a greater fluid flow rate adjacent proximal base **366**.

First wall extension **328** and second wall extension **332** are symmetrically disposed about septum extension **26** such that first cavity **56** and second cavity **62** are symmetrical. First cavity **56** and second cavity **62** bound an equivalent space to facilitate inflow and outflow capability for each lumen.

The configuration of catheter **10** advantageously facilitates reversible flow between first lumen **16** and second lumen **18** by alternating blood flow directions. As second lumen **18** expels blood flow for introduction to the body vessel, blood flow is forced out of second lumen **18**. The blood flow is axially directed out of cavity **62** past second wall extension **332**. It is envisioned that such axially directed blood flow washes away any blood clots disposed adjacent cavity **62**.

First lumen **16** is provided with suction to withdraw fluids from the body vessel. The suction draws blood flow from various directions and orientations into inlet opening **46**. Suction is greater adjacent proximal base **364** due to its closer proximity to a suction source (not shown). Fluid flow is greater adjacent to proximal base **364** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **62** of second lumen **18**. This configuration minimizes recirculation between lumens **16**, **18**.

It is contemplated that blood clots, or other undesired particles, disposed adjacent cavity **56** of first lumen **16** may be washed away by reversing blood flow direction of lumens **16**, **18**. Upon reversal of blood flow direction, blood flow is

expelled from cavity **56** and the axially directed blood flow washes away blood clots, similar to that described above.

Second lumen **18** is provided with suction to withdraw fluids from the body vessel and into opening **50**. Second wall extension **332** is symmetrical with first wall extension **328**, and therefore, similar to proximal base **364**, suction is greater adjacent proximal base **366**. Fluid flow is greater adjacent to proximal base **366** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **56**. This configuration minimizes recirculation between lumens **16**, **18**.

Referring to FIGS. **19-21**, another alternate embodiment of catheter **10** is shown, similar to that described above. First wall **22** includes a first wall extension **428** that extends distally beyond first lumen **16** and is spaced apart from septum extension **26**. First wall extension **428** defines a concave surface **430** that faces septum extension **26**. Second wall **24** includes a second wall extension **432** that extends distally beyond second lumen **18** and is spaced apart from septum extension **26**. Second wall extension **432** defines a concave surface **434** that faces septum extension **26**.

First wall extension **428** is circumferentially disposed about septum extension **26** in a spiral configuration to facilitate fluid flow and prevent recirculation between lumens **16**, **18**. It is envisioned that first wall extension **428** may include various spiral configurations, such as, for example, a more elongated spiral, a spiral having a more acute winding type design, helical, etc. First wall extension **428** extends distally, a distance aaa, beyond inlet opening **46** of first lumen **16** and outlet opening **50** (shown in phantom) of second lumen **18**. It is contemplated that distance aaa may extend various lengths. Concave surface **430** faces first planar surface **52** of septum extension **26** and is spaced apart therefrom.

Concave surface **430** is bounded by a planar end surface **454** of first wall extension **428**. End surface **454** extends about the perimeter of concave surface **430** in a spiral configuration, as described above, to facilitate fluid flow through first lumen **16**. Concave surface **430** and first planar surface **52** cooperate to define first cavity **56**, similar to that described above. First cavity **56** is further bounded by a proximal base **464** of end surface **454**. Proximal base **464** is formed with septum extension **26** in an arcuate transition. Proximal base **464** has an arcuate configuration and defines a proximal inlet portion for first lumen **16** during withdrawal of fluids. It is contemplated that suction provided with first lumen **16** has a greater fluid flow rate adjacent proximal base **464**.

Second wall extension **432** is circumferentially disposed about septum extension **26** in a spiral configuration to facilitate fluid flow and prevent recirculation between lumens **16**, **18**. It is envisioned that first wall extension **432** may include various spiral configurations, such as, for example, a more elongated spiral, a spiral having a more acute winding type design, helical, etc. Second wall extension **432** extends distally, a distance bbb, beyond outlet opening **50** (shown in phantom and similarly configured to inlet opening **46**) and inlet opening **46**. It is contemplated that distance bbb may extend various lengths. Concave surface **434** faces second planar surface **58**, opposing first planar surface **52**, of septum extension **26** and is spaced apart therefrom.

Concave surface **434** is bounded by a planar end surface **460** of second wall extension **432**. End surface **460** (similarly configured to end surface **454**, although end surfaces **454**, **460** may include alternative or distinct structure) extends about the perimeter of concave surface **434** in a spiral configuration, as described above, to facilitate fluid flow through second lumen **18**. Concave surface **434** and second planar surface **58** cooperate to define second cavity **62** (shown in phantom), similar to that described above. Second cavity **62** is further bounded by a proximal base **466** of end surface **460** (shown in phantom and similarly configured to base **464**, although bases **464**, **466** may include alternative or distinct structure). For example, if fluid flow is reversed with catheter **10**, proximal base **466** has an arcuate configuration and defines a proximal inlet portion for second lumen **18** during withdrawal of fluids. It is contemplated that suction provided with second lumen **18** has a greater fluid flow rate adjacent proximal base **466**.

First wall extension **428** and second wall extension **432** are symmetrically disposed about septum extension **26** such that first cavity **56** and second cavity **62** are symmetrical. First cavity **56** and second cavity **62** bound an equivalent space to facilitate inflow and outflow capability for each lumen.

The configuration of catheter **10** advantageously facilitates reversible flow between first lumen **16** and second lumen **18** by alternating blood flow directions. As second lumen **18** expels blood flow for introduction to the body vessel (shown by arrows A in FIG. **19**), blood flow is forced out of second lumen **18**. The blood flow is axially directed out of cavity **62** past second wall extension **432**. It is envisioned that such axially directed blood flow washes away any blood clots disposed adjacent cavity **62**.

First lumen **16** is provided with suction to withdraw fluids from the body vessel. The suction draws blood flow from various directions and orientations into inlet opening **46** (shown by arrows B in FIG. **19**). Suction is greater adjacent proximal base **464** due to its closer proximity to a suction source (not shown). Fluid flow is greater adjacent to proximal base **464** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **62** of second lumen **18**. This configuration minimizes recirculation between lumens **16**, **18**.

It is contemplated that blood clots, or other undesired particles, disposed adjacent cavity **56** of first lumen **16** may be washed away by reversing blood flow direction of lumens **16**, **18**. Upon reversal of blood flow direction, blood flow is expelled from cavity **56** and the axially directed blood flow washes away blood clots, similar to that described above.

Second lumen **18** is provided with suction to withdraw fluids from the body vessel and into opening **50**. Second wall extension **432** is symmetrical with first wall extension **428**, and therefore, similar to proximal base **464**, suction is greater adjacent proximal base **466**. Fluid flow is greater adjacent to proximal base **466** and therefore, advantageously disposed proximal to the blood flow being expelled from cavity **56**. This configuration minimizes recirculation between lumens **16**, **18**.

Referring to FIGS. **22-26**, another alternate embodiment of catheter **10** is shown, similar to that described above with regard to FIGS. **19-21**, that includes a third lumen **517**. Advantageously, third lumen **517** can be used with first and second lumens **16**, **18** including simultaneous and intermittent operation. Third lumen **517** may be employed for various utility, such as, for example, medication infusion, blood sampling, or pressure measurement in a vessel.

Third lumen **517** is coaxially disposed with a longitudinal center axis of tubular body **12**, and extends to distal end **14** beyond first lumen **16** and second lumen **18**. Third lumen **517** bisects septum **20** along a length thereof and has a substantially circular cross-section. The interior of third lumen **517** is defined by an annular surface **570** configured to facilitate fluid flow within lumen **517**. It is contemplated that third lumen **517** may also be configured for arterial and/or venous flow. It is envisioned that third lumen **517** may have various cross-sectional configurations, such as, for example, cylindrical, rectangular, elliptical, polygonal, etc. A number of such alter-

nate configurations are shown in FIGS. **26***a*-**26***i* and will be later described. Third lumen **517** may be also configured for various forms of fluid flow in various directions and orientations, according to the requirements of a particular catheter application.

Third lumen **517** may be uniformly dimensioned or include alternative dimensional cross sections within body **12**, such as, narrow and broad portions, converging surfaces, undulating surfaces, etc. according to the particular flow indications and/or flow rate requirements. It is contemplated that third lumen **517** may extend alternative lengths. It is further contemplated that body **12** may include additional lumens, such as, for example, a four lumen configuration (see, for example, FIG. **26***e*), etc.

Third lumen **517** includes a first opening, such as, for example, an outlet opening **572** that is disposed at distal end **14** of body **12**. An inlet opening (not shown) of third lumen **517** is disposed at proximal end **48** of body **12**. Outlet opening **572** is configured for expulsion of fluid and introduces such fluid into the blood vessel of a subject (not shown). Outlet opening **572** may be variously dimensioned and configured, such as, for example, rectangular, elliptical, polygonal, etc. and may include adapters, clips, etc. to facilitate fluid flow and/or attachment to other structure. It is contemplated that outlet opening **572** may also be configured for suction of fluid, or for other suitable purpose.

The exterior of third lumen **517** is defined by a first arcuate wall **574** and a second arcuate wall **576**. Third lumen **517** is separated from first lumen **16** by first arcuate wall **574**. This first arcuate wall **574** is bound along the length of third lumen **517** on either side by surface **40** of septum **20**. Arcuate wall **574** is bound at outlet opening **572** by a planar end surface **578**. End surface **578** extends about the perimeter of arcuate wall **574**.

Third lumen **517** is separated from second lumen **18** by second arcuate wall **576**. This second arcuate wall **576** is bound on either side along the length of third lumen **517** by septum surface **44**. Arcuate wall **576** is bound at outlet opening **572** also by planar end surface **578**. End surface **578** extends about the perimeter of arcuate wall **574**.

First wall **22** includes a first wall extension **528** that extends distally beyond first lumen **16** and is spaced apart from septum extension **26**. First wall extension **528** defines a concave surface **530** that faces septum extension **26**. Second wall **24** includes a second wall extension **532** that extends distally beyond second lumen **18** and is spaced apart from septum extension **26**. Second wall extension **532** defines a concave surface **534** that faces septum extension **26**.

A first blunt tip section **580** is disposed at the distal end of first wall extension **528**. First blunt tip section **580** extends along the distal perimeter of first wall extension **528** from septum surface **52** to planar end surface **554** in an arcuate configuration. A second first blunt tip section **582** (similarly configured to tip section **580**, although tip sections **580**, **582** may include alternative or distinct structure) is disposed at the distal end of second wall extension **528**. Second tip section **582** extends along the distal perimeter of second wall extension **532** from septum surface **52** to planar end surface **454** in an arcuate configuration. Advantageously, the blunt configuration of tip sections **580**, **582** is designed to prevent trauma to or "snagging" of the vessel wall. Alternatively, as shown in FIG. **26***a*, end surfaces **554**, **560** extend continuously in a smooth transition along the distal perimeter of respective wall extensions **528**, **532** to distal end **14**.

In each of the alternate embodiments shown in FIGS. **26***b* and **26***c*, third lumen **517** has a substantially wedge shaped cross-section. Third lumen **517** is separated from first lumen **16** by a wall **600**, and is separated from second lumen **18** by septum **20**. As shown in FIG. **26***b*, wall extensions **528**, **532** include blunt tip sections **580**, **582**. As shown in FIG. **26***c*, end surfaces **654**, **660** extend continuously with smooth transition along the distal perimeter of respective wall extensions **628**, **632**.

Each of the alternate embodiments shown in FIGS. **26***d* and **26***e* includes a fourth lumen **702** similar to third lumen **517**. Fourth lumen **702** has a substantially wedge shaped cross-section. Fourth lumen **702** is separated from second lumen **18** by wall **700**, and is separated from first lumen **16** by septum **20**. As shown in FIG. **26***d*, wall extensions **528**, **532** include blunt tip sections **580**, **582**. As shown in FIG. **26***e*, end surfaces **754**, **760** extend continuously in a smooth transition along the distal perimeter of respective wall extensions **728**, **732**.

In each of the alternative embodiments shown in FIGS. **26***f* and **26***g*, third lumen **517** is disposed longitudinally within first lumen **16**. Third lumen **517** bisects surface **40** of septum **20** along a length thereof and has a substantially circular cross-section. As shown in FIG. **26***f*, wall extensions **528**, **532** include blunt tip sections **580**, **582**. As shown in FIG. **26***g*, end surfaces **854**, **860** extend continuously in a smooth transition along the distal perimeter of respective wall extensions **828**, **832**.

In each of the alternative embodiments shown in FIGS. **26***h* and **26***i*, third lumen **517** has a substantially wedge shaped cross-section. Third lumen **517** is separated from first lumen **16** by a wall **900**, and is separated from second lumen **18** by a wall **902**. Walls **900**, **902** merge with septum **20** and septum extension **26**, and a wall extension **904** of body **12** define third lumen **517**. Third lumen **517** is disposed adjacent an end of septum extension **26**. As shown in FIG. **26***h*, wall extensions **528**, **532** include blunt tip sections **580**, **582**. As shown in FIG. **26***i*, end surfaces **954**, **960** extend continuously in a smooth transition along the distal perimeter of respective wall extensions **928**, **932**.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A catheter comprising:

an elongated tubular body defining a longitudinal axis and extending to a distal end thereof, the tubular body having a first lumen and a second lumen with a septum disposed therebetween, the tubular body including a first wall that defines the first lumen and a second wall that defines the second lumen, a portion of the septum extending distally beyond the first lumen and the second lumen;

wherein the first wall includes a first wall extension that extends in a spiral configuration from the first lumen about the longitudinal axis and is spaced apart from the portion of the septum; and

the tubular body having a third lumen.

2. A catheter as recited in claim **1**, wherein the third lumen is located coaxially along a longitudinal center axis of the tubular body.

3. A catheter as recited in claim **1**, wherein the third lumen has a substantially circular cross section.

4. A catheter as recited in claim **1**, wherein an exterior of the third lumen is defined by a first outer wall and a second outer wall, the third lumen is separated from the first lumen by said first outer wall, and the third lumen is separated from the second lumen by said second outer wall.

5. A catheter as recited in claim 4, wherein the first outer wall is bound along a length of the third lumen by a first surface of the septum, and the second outer wall is bound along the length of the third lumen by a second surface of the septum.

6. A catheter as recited in claim 1, wherein a portion of the third lumen extends distally beyond the first and second lumens.

7. A catheter as recited in claim 1, wherein the second wall includes a second wall extension that extends in a spiral configuration from the second lumen and is spaced apart from the portion of the septum.

8. A catheter as recited in claim 1, wherein the first wall extension includes a planar end surface that forms a boundary about the first wall extension and defines the spiral configuration of the first wall extension.

9. A catheter as recited in claim 7, wherein the first wall extension defines a first cavity and the second wall extension defines a second cavity, the first cavity and the second cavity being symmetrical.

10. A catheter as recited in claim 1, wherein the third lumen has a substantially wedge shaped cross section.

11. A catheter as recited in claim 10, wherein the wedge shaped third lumen is separated from said first lumen by a third outer wall, and is separated from said second lumen by said septum.

12. A catheter comprising:

an elongated tubular body defining a longitudinal axis and extending to a distal end thereof, the tubular body having a first lumen and a second lumen with a septum disposed therebetween, the tubular body including a first wall that defines the first lumen and a second wall that defines the second lumen, a portion of the septum extending distally beyond the first lumen and the second lumen;

wherein the first wall includes a first wall extension that extends in a spiral configuration from the first lumen about the longitudinal axis and is spaced apart from the portion of the septum; and

the tubular body includes a third lumen which extends distally beyond the first wall extension.

13. A catheter as recited in claim 12, wherein the first wall extension defines a concave surface facing said portion of the septum and includes a planar surface that forms a boundary about said concave surface and defines the spiral configuration of the first wall extension.

14. A catheter as recited in claim 12, wherein the third lumen is located coaxially along a longitudinal center axis of the tubular body.

15. A catheter as recited in claim 12, wherein the third lumen has a substantially circular cross section.

16. A catheter as recited in claim 12, wherein an exterior of the third lumen is defined by a first outer wall and a second outer wall, the third lumen is separated from the first lumen by said first outer wall, and the third lumen is separated from the second lumen by said second outer wall.

17. A catheter as recited in claim 16, wherein the first outer wall is bound along a length of the third lumen by a first surface of the septum, and the second outer wall is bound along the length of the third lumen by a second surface of the septum.

18. A catheter as recited in claim 12, wherein a portion of the third lumen extends distally beyond said first and second lumens.

19. A catheter as recited in claim 12, wherein the third lumen has a substantially wedge shaped cross section.

20. A catheter as recited in claim 19, wherein the wedge shaped third lumen is separated from said first lumen by a third outer wall, and is separated from said second lumen by said septum.

21. A catheter comprising:

an elongated tubular body defining a longitudinal axis and extending to a distal end thereof, the tubular body having a first lumen and a second lumen with a septum disposed therebetween, the tubular body including a first wall that defines the first lumen and a second wall that defines the second lumen, a portion of the septum extending distally beyond the first lumen and the second lumen;

wherein the first wall includes a first wall extension that extends in a spiral configuration from the first lumen about the longitudinal axis and is spaced apart from the portion of the septum; and

the tubular body having a third lumen of substantially circular cross section and extending distally beyond the first and second lumens, said third lumen located coaxially along a center longitudinal axis of said tubular body so to bisect said septum,

an exterior of the third lumen is defined by a first arcuate wall and a second arcuate wall, the third lumen is separated from the first lumen by said first arcuate wall, and the third lumen is separated from the second lumen by said second arcuate wall.

22. A catheter comprising:

an elongated tubular body defining a longitudinal axis and extending to a distal end thereof, the tubular body having a first lumen and a second lumen with a septum disposed therebetween, the tubular body including a first wall that defines the first lumen and a second wall that defines the second lumen, a portion of the septum extending distally beyond the first lumen and the second lumen;

wherein the first wall includes a first wall extension that extends in a spiral configuration from the first lumen about the longitudinal axis and is separated from the portion of the septum,

a blunt tip section is disposed at a distal end of said first wall extension; and

the tubular body has a third lumen.

23. A catheter as recited in claim 22, wherein said first tip section extends about a distal perimeter of said first wall extension from a surface of said septum to an end surface of said first wall extension in an arcuate configuration.

24. A catheter as recited in claim 22, wherein the third lumen is located coaxially along a longitudinal center axis of the tubular body.

25. A catheter as recited in claim 22, wherein the third lumen has a substantially circular cross section.

26. A catheter as recited in claim 22, wherein an exterior of the third lumen is defined by a first outer wall and a second outer wall, the third lumen is separated from the first lumen by said first outer wall, the third lumen is separated from the second lumen by said second outer wall.

27. A catheter as recited in claim 26, wherein the first outer wall is bound along a length of the third lumen by a first surface of the septum, and the second outer wall is bound along the length of the third lumen by a second surface of the septum.

28. A catheter as recited in claim 22, wherein a portion of the third lumen extends distally beyond said first and second lumens.

29. A catheter as recited in claim 22, wherein the third lumen has a substantially wedge shape cross section.

30. A catheter as recited in claim 29, wherein the wedge shaped third lumen is separated from said first lumen by a third outer wall, and is separated from said second lumen by said septum.

31. A catheter as recited in claim 22, wherein the second wall includes a second wall extension that extends in a spiral configuration from the second lumen and is spaced apart from the portion of the septum, and a second blunt tip section is disposed at a distal end of said second wall extension.

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